DEFERRED PROSECUTION AGREEMENT

1. The United States Attorney's Office for the District of New Jersey and the Consumer Protection Branch of the United States Department of Justice (the "Offices") will file, on or shortly after the Effective Date of this deferred prosecution agreement (the "DPA" or this "Agreement"), a criminal complaint in the United States District Court for the District of New Jersey charging Pentax of America, Inc., doing business as Pentax Medical Company ("the Company"), with the introduction into interstate commerce of misbranded medical devices, as provided in 21 U.S.C. §§ 352(f) and 352(t)(2), in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(1) (the "Criminal Complaint"). The Company is an indirect wholly-owned subsidiary of HOYA Corporation ("HOYA"), which includes the PENTAX Lifecare Division ("PENTAX Global"). As such, HOYA, through PENTAX Global, has the authority to effect compliance initiatives and measures at the Company.

2. In order to resolve the charges contained in the Criminal Complaint, the Offices and the Company, pursuant to authority granted to its undersigned representatives by the Company's Board of Directors, enter into this DPA. HOYA, pursuant to authority granted to its undersigned representatives by HOYA's Board of Directors, also agrees to certain terms and obligations of the Agreement as described below.

3. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Criminal Complaint, and as set forth in Attachment A, and that the allegations in the Criminal Complaint and the facts set forth in the Statement of Facts in Attachment A (the "Statement of Facts") are true and accurate. Should the Offices pursue the prosecution that is deferred by this Agreement, the Company stipulates to the admissibility of the Statement of Facts as an

admission in any proceeding, including any trial, guilty plea, or sentencing proceeding, and will not contest or contradict anything in the Statement of Facts at any such proceeding.

4. Except as specifically provided below, the DPA shall be in effect for a period of 36 months from the date on which it is fully executed (the "Effective Date"). The Company and the Offices agree, however, that in the event the Offices determine, in their sole discretion, that the Company has knowingly breached any provision of this DPA as defined in paragraphs 27 and 28, the Offices may, in their sole discretion, extend the term of this DPA by a period of up to 24 months, with a total term not to exceed 60 months, without prejudice to the Offices' right to proceed as provided in paragraphs 27 to 29 below. Conversely, in the event the Offices find, in their sole discretion, that there exists a change in circumstances sufficient to eliminate the need for the continuing effect of this Agreement, the Offices may terminate this Agreement early.

5. Within 10 days of the Effective Date, the Company shall pay a criminal fine in the amount of $40,000,000 and shall pay criminal forfeiture in the amount of $3,000,000.

6. Upon the filing of the Criminal Complaint, this DPA shall be publicly filed in the United States District Court for the District of New Jersey, and the Company will post the DPA prominently on the Company website for the duration of the DPA. The Company also shall distribute copies of the DPA to all Company employees.

7. The Offices enter into this Agreement based on the individual facts and circumstances presented in this case, including:

a. the Company did not receive self-reporting credit because it reported conduct to the Offices after receiving a subpoena and therefore did not voluntarily and timely disclose to the Offices all of the conduct described in the Statement of Facts;

b. the Company received full credit for its cooperation with the Offices' investigation, including: conducting a thorough internal investigation, making regular factual presentations to the Offices, proactively identifying issues and facts that would likely be of interest to the Offices, advising the Offices about facts and issues that were not the focus of the subpoena, and collecting, analyzing, and organizing voluminous evidence and information for the Offices;

c. the Company voluntarily provided to the Offices relevant facts known to it;

d. the Company submitted Medical Device Reports ("MDRs") to the Food and Drug Administration ("FDA") before the investigation started for the adverse incidents described in the Statement of Facts, although the Medical Device Reports were filed several months late;

e. the Company voluntarily advised the FDA about the failure to ship approved instructions for use ("IFUs") and then fully disclosed this issue to the Offices;

f. the Company represents that it has engaged in remedial measures, including recalling and replacing the instructions for use improperly shipped from April 2014 through September 2015 and seeking FDA approval for enhanced instructions for use that comply with FDA requirements;

g. the Company represents that it has enhanced and has committed to continuing to enhance its compliance program, including hiring a new Chief Compliance Officer and a new Vice President of Quality Assurance and Regulatory Affairs, updating its policies and procedures, revamping its system for preparing Medical Device Reports, increasing training in compliance with

federal health care laws, enhancing its processes and controls, employing outside counsel and health care compliance consultants, and increasing the infrastructure, personnel, and resources dedicated to compliance;

h. based on the Company's remediation and the state of its compliance program, and the Company's agreement to the compliance and reporting obligations set forth in Attachment B, the Offices determined that an independent compliance monitor is not necessary;

i. the nature and seriousness of the offense conduct; and

j. the Company has agreed to continue to cooperate with the Offices in any ongoing investigation of the conduct of the Company, its subsidiaries, and affiliates and its officers, directors, employees, agents, and business partners.

In light of these factors and the Company's agreement to this DPA, the Offices shall recommend to the Court that prosecution of the Company on the Criminal Complaint be deferred for a period of 36 months from the Effective Date of this DPA. If the Court declines to defer prosecution for any reason, this DPA shall be null and void, and the parties will revert to their pre-DPA positions.

8. The Company shall not, through its present or future attorneys, Board of Directors, officers, employees, or agents, make any public statement contradicting any fact contained in the Statement of Facts. The Offices shall have the sole discretion to decide whether any public statement contradicting a fact contained in the Statement of Facts will be imputed to the Company. If the Offices determine that the Company has made a public statement contradicting any fact contained in the Statement of Facts, the Offices shall so notify the Company. Thereafter, the Company may avoid a breach by publicly repudiating the statement

within 48 hours after such notification. Any such contradictory public statement, if not repudiated by the Company, will constitute a breach as governed by paragraphs 27 and 28 of this Agreement, and the Company thereafter will be subject to prosecution pursuant to the terms of this Agreement. This paragraph does not apply to any statement made by any present or former Company officer, director, employee, or agent, in any proceeding in an individual capacity and not on behalf of the Company. The Company shall be permitted to raise defenses and to assert affirmative claims in civil, regulatory, and other proceedings related to the matters set forth in the Statement of Facts, provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts.

General Commitment to Compliance and Remedial Actions

9. The Company commits itself to exemplary corporate citizenship, best practices of effective corporate governance, the highest principles of honesty and professionalism, the integrity of the operation of federal health care programs, and a culture of openness, accountability, and compliance throughout the Company. The Company represents that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of federal health care law, including but not limited to the compliance and remediation measures stated in this Agreement and in Attachment B.

10. The Company shall communicate to its employees and customers that Company personnel and agents are required to report to the Company any suspected violations of any federal laws, regulations, federal health care program requirements, or internal policies and procedures.

11. The Company shall continue to develop, operate, and enhance an effective corporate compliance program and function to ensure that policies, procedures, and internal controls are in place to prevent recurrence of the activities that resulted in this DPA. The

Company also shall continue to develop and implement policies, procedures, and practices designed to ensure compliance with federal health care laws. The Company also shall continue to develop and implement mechanisms that will (a) test periodically the effectiveness of its corporate compliance program through internal monitoring, auditing, and risk assessments; (b) detect violations of its compliance policies; and (c) enforce violations of its compliance policies through disciplinary procedures.

12. The PENTAX Global President, PENTAX Global General Counsel or alternative HOYA General Counsel, PENTAX Global Head of Regulatory Affairs and Quality Assurance, HOYA Global Chief Compliance Officer, PENTAX Global Chief Compliance Officer, the Company's President, the Company's Vice President of Regulatory Affairs and Quality Assurance, and other appropriate Company executives will meet annually with the Offices and counsel for the FDA, unless the Offices conclude that a meeting is not necessary. The first meeting shall take place 30 days after the submission of the Annual Management Certification and Annual Board of Directors Resolution required by paragraphs 17-19 and 21-23. At such meetings, which may be conducted telephonically at the discretion of the Offices, Company executives will make presentations and answer questions about the Company's compliance with this DPA.

13. The Company shall promptly notify the Offices in writing of any credible evidence of criminal conduct or serious wrongdoing by, or criminal investigations of, the Company, its officers, directors, employees and agents, of any type that becomes known to the Company after the Effective Date. Upon request, the Company shall provide the Offices with all relevant non-privileged documents and information concerning such allegations, including but not limited to internal audit reports, letters threatening litigation, "whistleblower" complaints,

civil complaints, and documents produced in civil litigation. In addition, the Company shall report to the Offices concerning its planned investigative measures and any findings and resulting remedial measures.

Responsibilities of Chief Compliance Officer

14. The PENTAX Global Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities of the Company. The PENTAX Global Chief Compliance Officer shall report directly to the HOYA Global Chief Compliance Officer and the PENTAX Global President. The HOYA Global Chief Compliance Officer shall in turn report directly to the HOYA Board of Directors and to the HOYA Chief Executive Officer, and shall not be subordinate in function or position to the General Counsel or the legal department or any sales or marketing officers, in any manner. The HOYA Global Chief Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters to the HOYA Board of Directors and is authorized to report on such matters directly to the HOYA Board of Directors at any time.

15. The HOYA Global Chief Compliance Officer and the PENTAX Global Chief Compliance Officer shall have the authority to meet with, and require reports and certifications on any subject from, any officer or employee of the Company.

Compliance Training

16. The Company will continue to maintain, support, and enhance its existing training and education programs. The programs, which shall be reviewed and approved by the HOYA Board of Directors, HOYA Global Chief Compliance Officer, the PENTAX Global President, the PENTAX Global General Counsel or alternative HOYA General Counsel, the PENTAX Global Chief Compliance Officer, and the Company's President shall be designed to advance and underscore the Company's commitment to exemplary corporate citizenship, best practices of

effective corporate governance, and the highest principles of integrity and professionalism, and to fostering a culture of openness, accountability, and compliance with federal health care laws throughout the Company. Completion of such training shall be mandatory for all Company officers, executives, and employees who are involved in Sales, Marketing, Legal, Regulatory, and Compliance activities related to the Company's medical and surgical business, and other senior executives at the Company (collectively, the "Mandatory Participants"). Such training and education shall cover, at a minimum, all relevant federal health care laws and regulations, and the obligations assumed by, and responses expected of, the Mandatory Participants upon learning of improper, illegal, or potentially illegal acts relating to the Company's practices. The PENTAX Global President, the Company's President, and HOYA Board of Directors shall communicate, in writing or by video, their review and endorsement of the training and education programs to the Mandatory Participants. The Company shall commence providing this training within 120 calendar days after the Effective Date of this DPA.

Annual Management Certification

17. The PENTAX Global President and the Company's President shall conduct an annual review of the Company's Compliance Program during the preceding year. The first review period shall run from the Effective Date through 10 months after the Effective Date. Thereafter, the reviews will be conducted on an annual basis.

18. The PENTAX Global President and the Company's President shall submit to the Offices a signed certification stating that based on his or her review and to the best of his or her knowledge, during the period *[insert time period]*: (1) the Company's Compliance Program included the policies and procedures set forth in this Agreement; (2) the Company maintained all necessary MDR Compliance Measures described in Attachment B; (3) the Company conducted an effective IFU Review as required by Attachment B; and (4) the Compliance Program was

effective in preventing, detecting, and/or remediating, where necessary, violations of federal health care laws.

19. The PENTAX Global President and the Company's President's certification shall summarize the review described above that he or she conducted to provide the required certification. If the PENTAX Global President and the Company's President are unable to provide any of the certifications required by paragraph 18, they shall explain in detail why the certifications could not be provided and explain the steps the Company is taking to ensure the completion of the measures required by Attachment B and the effectiveness of the Compliance Program. This explanation will satisfy the certification requirement with regard to the Compliance Program.

Executive Financial Recoupment Program

20. The Company, PENTAX Global President, and PENTAX Global Chief Financial Officer agree to establish an executive financial recoupment program that requires (a) Company executives or (b) PENTAX Global executives who engage in misconduct within the scope of this Agreement, or whose failure to effectively supervise or promote compliance contributes to misconduct within the scope of this Agreement, to forfeit up to three years of their annual performance pay.

Annual Board of Directors Resolution

21. The HOYA Board of Directors, or the Committee it designates (the "Board"), shall review annually the effectiveness of the Company's Compliance Program, which shall include a review of the Company's MDR Compliance Measures, the IFU Review, and other policies and procedures required by this DPA. This review shall include, but not be limited to, briefings and reports by the HOYA Global Chief Compliance Officer, the PENTAX Global Chief Compliance Officer, and other compliance personnel. The Board shall evaluate the

Compliance Program by, among other means, reviewing the activities of the HOYA Global Chief Compliance Officer, PENTAX Global's Chief Compliance Officer, and other Company personnel, and by reviewing the adoption and implementation of policies, procedures, and practices designed to ensure compliance with federal health care laws.

22. The first review will cover the time period from the Effective Date of this Agreement through 10 months after the Effective Date. Based on its review, the Board shall submit to the Offices a resolution (the "Board Resolution") that summarizes its review and oversight of the Company's Compliance Program and, at a minimum, includes the following language:

> The Board of Directors has made a reasonable inquiry into the content and operations of the Compliance Program for Pentax of America, Inc. during the time period *[insert time period]*, including the performance of the Chief Compliance Officer and other compliance personnel. The Board has concluded that, to the best of its knowledge, Pentax of America, Inc. has implemented a Compliance Program designed to exercise due diligence to prevent, detect, and remediate misconduct, including violations of the Federal Food, Drug & Cosmetic Act and its implementing regulations and other federal health care laws, and is promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law. Pentax of America, Inc.'s Compliance Program continued to include the policies and procedures set forth in the Deferred Prosecution Agreement with the United States, dated _____, 2020.

If the Board is unable to provide any part of this statement, it shall include an explanation in the resolution.

23. The Company shall provide the PENTAX Global President's and the Company's President's Certification and the Board Resolution to the Offices within 60 calendar days following the end of each review period.

Hotline and Website

24. The Company agrees to maintain a confidential hotline and website, of which Company employees, agents, and customers are informed, and which they can use to notify the Company of any concerns about unlawful conduct, other wrongdoing, or evidence that Company

practices do not conform to the requirements of this Agreement. The Company shall post information about this hotline on its website and shall inform all those who avail themselves of the hotline of the Company's commitment to non-retaliation and to maintaining confidentiality and anonymity with respect to such reports.

Notification to Healthcare Providers

25. Within 90 days after the Effective Date, the Company will provide notice of this Agreement to all customers in the United States to whom the Company distributed duodenoscopes during July through September 2013 and July through December 2014 and to whom the Company distributed colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes during April 2014 through September 2015. Specifically, the Company shall send, by first class mail, postage prepaid, a notice containing the language set forth below:

> "In ___ 2020, Pentax of America, Inc. entered into a Deferred Prosecution Agreement with the U.S. Attorney for the District of New Jersey and the Consumer Protection Branch of the U.S. Department of Justice in connection with Pentax's failure to timely inform the Food and Drug Administration about adverse events involving its duodenoscope in 2013 and 2014 and its failure to include FDA-approved instructions for use in four types of endoscopes shipped from April 2014 through September 2015. Pentax has admitted that it failed to timely file Medical Device Reports ("MDRs") with the FDA in connection with two incidents. Pentax also has admitted that for a period of 18 months, Pentax shipped colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes with older instructions for use instead of the instructions for use that had been approved by the FDA. This letter gives you additional information about this Agreement.
>
> Federal law requires a medical device manufacturer such as Pentax to submit MDRs to the FDA, generally within 30 days, when it learns that one of its marketed devices may have caused or contributed to a death or serious injury, or malfunctioned and such a malfunction would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Federal law also requires a medical device manufacturer to include instructions for use approved by the FDA when shipping medical devices to customers.
>
> In June 2013, Pentax learned that four patients were infected with bacteria after being treated with the same Pentax duodenoscope, but Pentax did not file an MDR with the FDA until September 2013. In June 2014, Pentax learned that another four patients at a different hospital were infected with bacteria after being treated with a Pentax

duodenoscope, but Pentax did not file an MDR until December 2014. Because Pentax did not make the required MDR filings, all duodenoscopes distributed by Pentax between July and September 2013 and July and December 2014 were "misbranded" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and their distribution was thus in violation of the FDCA.

In April 2014, the FDA approved revised instructions for use for four Pentax endoscopes – colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes. The revisions included additional cleaning steps. Pentax was required to include these revised instructions for use when it shipped these four endoscopes, but Pentax failed to do so through September 2015. Because the shipment of these medical devices did not include the FDA-approved instructions for use, the four scopes were misbranded, and their distribution during this period also violated the FDCA.

Pentax admitted this conduct in the Deferred Prosecution Agreement. Pentax has agreed to pay a criminal fine and forfeiture of $43 million, enact enhanced compliance measures, and regularly make certain certifications. These measures were designed to promote compliance with FDCA and Federal health care program requirements. Pentax also agreed to provide this notice to Health Care Providers. The Deferred Prosecution Agreement can be found at [Pentax shall include a link to the DPA on its website].

You may report any improper conduct associated with device marketing to the FDA's Center for Devices and Radiological Health (CDRH) Allegations of Regulatory Misconduct Branch at OCMedicalDeviceCO@fda.hhs.gov."

Cooperation

26. In matters relating to federal health care laws, the Company will cooperate fully with all federal law enforcement and regulatory agencies, including but not limited to: the Criminal and Civil Divisions of the Offices; the United States Department of Justice, Criminal and Civil Divisions; the FDA; Department of Health and Human Services, Office of Inspector General; and the Federal Bureau of Investigation; provided, however, that such cooperation shall not require the Company's waiver of attorney-client and work product protections or any other applicable legal privileges. Nothing in this DPA shall be construed as a waiver of any applicable attorney-client or work product privileges. The Company's future cooperation is an important factor in the decision of the Offices to enter into this DPA, and the Company will continue to cooperate fully with the Offices, and with any other government agency designated by the

Offices, regarding any issue about which the Company has knowledge or information with respect to compliance with federal health care laws. The Company agrees that its continuing cooperation during the term of this DPA shall include, but shall not be limited to, the following:

a. Not engaging in or attempting to engage in any criminal conduct;

b. Completely, truthfully, and promptly disclosing all non-privileged information concerning all matters about which the Offices and other government agencies designated by the Offices may inquire with respect to the Company's compliance with federal health care laws, and continuing to provide the Offices, upon request, all non-privileged documents and other materials relating to such inquiries;

c. Making available current Company officers and employees and using its best efforts to make available former Company officers and employees to provide information and/or testimony at all reasonable times as requested by the Offices, including sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities as may relate to matters involving compliance with health care laws. The Company is not required to request of its current or former officers and employees that they forego seeking the advice of an attorney or that they act contrary to that advice. Cooperation under this paragraph shall include, upon request, identification of witnesses who, to the Company's knowledge, may have material non-privileged information regarding the matters under investigation;

d. Providing testimony, certifications, and other non-privileged information deemed necessary by the Offices or a court to identify or establish the original

location, authenticity, or other evidentiary foundation necessary to admit into evidence documents in any criminal or other proceeding relating to compliance with federal health care laws;

e. This agreement to cooperate does not apply to any communications between the Company and its legal counsel in connection with the provision of legal advice and the legal advice itself, or to information or documents prepared in anticipation of litigation, and nothing in this DPA shall be construed to require the Company to provide any such information or advice to the Offices or any other government agency; and

f. The cooperation provisions in this Agreement shall no longer apply in the event that the Offices pursue a criminal prosecution against the Company related to the Criminal Complaint.

Breach of Agreement

27. Should the Offices determine, in good faith and in their sole discretion, during the term of this DPA that the Company has committed any criminal conduct subsequent to the Effective Date of this DPA, the Company shall, in the discretion of the Offices, thereafter be subject to prosecution for any federal crimes of which the Offices have knowledge, including crimes relating to the matters set forth in the Criminal Complaint and the Statement of Facts.

28. Should the Offices determine in good faith and in their sole discretion that the Company has knowingly and willfully breached any material provision of this DPA, the Offices shall provide written notice to the Company of the alleged breach and provide the Company with a three-week period from receipt of such notice in which to make a presentation to the Offices to demonstrate that no breach occurred, that the breach was not material or knowingly and willfully committed, or that the breach has been cured. Should the Company fail to make a presentation to

the Offices within the three-week period after receiving written notice of an alleged breach, or by any other date agreed by the Offices and the Company, it shall be conclusively presumed that the Company is in breach of this DPA. The determination whether the Company has breached this DPA rests solely in the discretion of the Offices, and the exercise of discretion by the Offices under this paragraph is not subject to review in any court or tribunal. In the event of any breach of this DPA, any resulting prosecution of the Company may be premised upon any information provided by or on behalf of the Company to the Offices at any time, unless otherwise agreed at the time the information was provided.

29. In the event that the Offices determine that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Offices or to the Court, including the attached Statement of Facts, and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Offices against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Offices.

Waivers and Limitations

30. The Company expressly waives all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, Title 18, United States Code, Section 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the District of New Jersey, for the period that this DPA is in effect for any prosecution of the Company relating to the allegations set forth in the Criminal Complaint and the Statement of Facts.

31. If the Offices undertake a prosecution under paragraphs 27 and 28, any prosecution of the Company relating to the allegations set forth in the Criminal Complaint and the Statement of Facts that is not time-barred by the applicable statute of limitations as of the Effective Date of this DPA may be commenced against the Company notwithstanding the expiration of any applicable statute of limitations during the term of the DPA. The Company agrees to waive any claims of improper venue with respect to any prosecution of the Company relating to the allegations set forth in the Criminal Complaint and the Statement of Facts. This waiver is knowing and voluntary and in express reliance on the advice of counsel. Any such waiver shall terminate upon final expiration of this DPA.

32. Absent the express written consent of the Offices, if, after the Effective Date of this Agreement, the Company sells all or substantially all of its business operations as they exist as of the Effective Date of this Agreement to a single purchaser or group of affiliated purchasers during the term of this Agreement, or merges with a third party in a transaction in which the Company is not the surviving entity, the Company shall include in any contract for such sale or merger a provision binding the purchaser, successor, or surviving entity to continue to comply with the Company's obligations as contained in this DPA.

33. Nothing in this DPA restricts in any way the ability of the Offices to investigate and prosecute any current or former Company officer, employee, agent, or attorney.

Dismissal of Criminal Complaint

34. If the Company complies fully with all of its obligations under this DPA, the Offices will seek dismissal with prejudice of the Criminal Complaint within 30 days of the expiration of the term of this DPA.

35. Except as otherwise provided in this Agreement, during and upon the conclusion of the term of this DPA, the Offices will not prosecute the Company further for conduct that (1) falls within the scope of the Offices' investigation of violations of the FDCA, or (2) the Company brought to the Offices' attention during the investigation. The non-prosecution provisions of this DPA specifically exclude any actions taken by the United States, civil or criminal, relating to federal tax matters.

Binding Effect of this Agreement

36. This Agreement is binding on the Company and the Offices, but specifically does not bind any other component of the United States Department of Justice, other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the Offices will bring the cooperation of the Company and its compliance with this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

Notices

37. Any notice to the Offices and Submissions, reports, or filings to FDA-CDRH under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Chief, Health Care Fraud Unit
United States Attorney's Office
District of New Jersey
970 Broad Street, 7th Floor
Newark, NJ 07102

Director
Consumer Protection Branch
U.S. Department of Justice
450 5th Street NW, 6th Floor South
Washington, DC 20001

Erin Keith
FDA/CDRH/ODE
WO 66, Rm. 2516
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Any notice to the Company under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Neil H. MacBride, Esquire
Davis Polk & Wardwell LLP
901 15th Street NW
Washington, DC 20005

The Full Agreement

38. This DPA constitutes the full and complete agreement between the Company and the Offices and supersedes any previous agreement between them. The Company and the Offices have not agreed to any additional promises, agreements, or conditions other than those set forth in this DPA, and none will be binding unless in writing and signed by the Offices, Company counsel, and a duly authorized representative of the Company. The Offices may permit exceptions to or excuse particular requirements set forth in this DPA at the written request of the Company, but any such permission shall be in writing.

39. This DPA may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same agreement. The

exchange of copies of this DPA and of signature pages by facsimile or electronic transmission shall constitute effective execution and delivery of this DPA as to the parties and may be used in lieu of the original DPA for all purposes. Signatures of the parties transmitted by facsimile or electronic transmission shall be deemed to be their original signatures for all purposes.

AGREED:

FOR PENTAX OF AMERICA, INC., DOING BUSINESS AS PENTAX MEDICAL COMPANY

Date: _____ By: _____

David Woods
President
Pentax of America, Inc. doing business as
Pentax Medical Company

Date: _____ By: _____

Neil H. MacBride, Esq.
Martine M. Beamon, Esq.
Davis Polk & Wardwell LLP

FOR HOYA CORPORATION

Date: _____ By: _____

Hiroshi Suzuki
President and Chief Executive Officer
HOYA Corporation

Date: _____ By: _____

Neil H. MacBride, Esq.
Martine M. Beamon, Esq.
Davis Polk & Wardwell LLP

FOR THE DEPARTMENT OF JUSTICE:

CRAIG CARPENITO
United States Attorney
District of New Jersey

Date: _____ By: _____

R. David Walk, Jr.
Assistant United States Attorney

GUSTAV W. EYLER
Director
Consumer Protection Branch
U.S. Department of Justice

Date: _____ By: _____

Patrick Jasperse
Senior Litigation Counsel
Consumer Protection Branch
U.S. Department of Justice

DIRECTOR'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Pentax of America, Inc., doing business as Pentax Medical Company (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am a Director of the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

Date: _____

Pentax of America, Inc., doing business as Pentax Medical Company

By: _____
David Woods
Director

DIRECTOR'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with counsel to HOYA Corporation ("HOYA") (including outside counsel for HOYA). I understand the terms of this Agreement and voluntarily agree, on behalf of HOYA, to each of its terms. Before signing this Agreement, I consulted with counsel to HOYA (including outside counsel for HOYA). Counsel fully advised me of the rights of HOYA, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have advised and caused counsel to HOYA (including outside counsel for HOYA) to advise the Board of Directors fully of the rights of HOYA, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of HOYA, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am a Director of HOYA and that I have been duly authorized by HOYA to execute this Agreement on behalf of HOYA.

Date: _____

HOYA Corporation

By: _____
Hiroshi Suzuki
Director

CERTIFICATE OF COUNSEL

I am counsel for Pentax of America, Inc., doing business as Pentax Medical Company (the "Company"), and HOYA Corporation ("HOYA") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company's and HOYA's Boards of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of the Company and the representative of HOYA have been duly authorized to enter into this Agreement on behalf of the Company and HOYA and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and HOYA and that it is a valid and binding obligation of the Company and HOYA. Further, I or counsel to HOYA have carefully reviewed the terms of this Agreement with the Boards of Directors of the Company and HOYA, as well as the General Counsel of HOYA Corporation for PENTAX Lifecare Division. I have fully advised them of the rights of the Company and HOYA, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Boards of Directors, is informed and voluntary.

Date: _____

By: _____

Neil H. MacBride
Davis Polk & Wardwell LLP
Counsel for Pentax of America, Inc., doing business as
Pentax Medical Company, and HOYA Corporation

CERTIFIED COPY OF RESOLUTION

Upon the unanimous written consent of all the Directors in accordance with Delaware General Corporation Law, the following resolution was adopted:

WHEREAS, Pentax of America, Inc., doing business as Pentax Medical Company (the "Company") has been engaged in discussions with the United States Attorney's Office for the District of New Jersey and the Department of Justice, Civil Division, Consumer Protection Branch (the "Offices") in connection with an investigation being conducted by the Offices and

WHEREAS, the Board of the Company consents to resolution of these discussions by entering into a Deferred Prosecution Agreement that the Company's Board of Directors has reviewed with outside counsel representing the Company, relating to a criminal complaint to be filed in the United States District Court for the District of New Jersey charging the Company with the introduction into interstate commerce of misbranded medical devices (pursuant to 21 U.S.C. §§ 352(f) and 352(t)(2)) in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(1);

NOW, THEREFORE, BE IT RESOLVED that outside counsel representing the Company from Davis Polk & Wardwell LLP be, and they hereby are authorized, empowered, and directed to execute a Deferred Prosecution Agreement on behalf of the Company substantially in the same form as reviewed by the Company's Board of Directors and attached as Exhibit A, and that a Director of this Company is authorized to execute the attached Director's Certificate.

DIRECTOR'S CERTIFICATION

I, David Woods, a director of Pentax of America, Inc., doing business as Pentax Medical Company (the "Company"), a corporation organized under the laws of the State of Delaware, hereby certify that the attached document is a true and exact copy of a resolution approved by the Board of Directors of the Company via unanimous written consent on [insert date]:

IN WITNESS WHEREOF, I have hereunto signed my name and caused the Seal of said Corporation to be affixed on this ____ day of ___ 2020.

_____

David Woods, Director

ATTACHMENT A

STATEMENT OF FACTS

Summary

1. PENTAX OF AMERICA, INC., doing business as PENTAX MEDICAL COMPANY ("PENTAX"), which has its principal place of business in Montvale, New Jersey, is a United States subsidiary of HOYA, a medical technology corporation based in Tokyo, Japan.

2. PENTAX manufactures and distributes medical devices, including endoscopes. An endoscope is a thin, flexible tube with a powerful light and a tiny camera that is inserted into the body to give a physician a view of the internal parts of a patient's body. Endoscopes may have instruments at the end of the tube that physicians use to perform surgical procedures. Among the endoscopes that PENTAX manufactures and distributes are duodenoscopes, colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes.

3. From 2013 to 2015, within the District of New Jersey, and elsewhere, acting through its employees, including senior managers, PENTAX introduced and delivered for introduction into interstate commerce medical devices that were misbranded, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(1).

    a. From on or about July 25, 2013, until on or about September 20, 2013, and from on or about July 27, 2014, until on or about December 15, 2014, PENTAX failed to file required Medical Device Reports ("MDRs") with the U.S. Food and Drug Administration ("FDA") about adverse events involving PENTAX's duodenoscope. The shipment of duodenoscopes for which information required by the FDCA had not been furnished rendered the medical devices misbranded, pursuant to 21 U.S.C. § 352(t)(2).

    b. From on or about April 9, 2014, until on or about September 30, 2015, PENTAX distributed four types of endoscopes in the United States with unapproved instructions for use ("IFUs"). The shipment of endoscopes with inadequate instructions for use rendered the medical devices misbranded, pursuant to 21 U.S.C. § 352(f).

Failure to Timely File Medical Device Reports

The FDA and the FDCA

4. The FDA is responsible for protecting the health and safety of the American public by assuring, among other things, that medical devices intended for use in the treatment of human beings are safe and effective for their intended uses. Pursuant to its statutory mandate, the FDA regulates the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

5. The FDCA, among other things, governs the manufacture and interstate distribution of medical devices for human use, as codified at 21 U.S.C. §§ 301-399f.

6. The FDCA and its implementing regulations provide a mechanism that allows FDA, and others, to identify and monitor adverse events (deaths and serious injuries) and certain malfunctions involving medical devices. Pursuant to 21 U.S.C. § 360i(a) and 21 CFR Part 803, medical device manufacturers must (1) develop, maintain, and implement written procedures for the identification and evaluation of all malfunctions, serious injuries, and deaths to determine whether an MDR is required for an event; (2) submit MDR reportable events involving their medical devices to the FDA; and (3) establish and maintain complete files for all MDR events.

7. Manufacturers must file an MDR with the FDA within thirty (30) days of receiving or becoming aware of information that reasonably suggests that a device the manufacturer markets (a) may have caused or contributed to a death or serious injury or (b) has malfunctioned, and the device or a similar device the manufacturer markets would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

8. MDRs are one of the post-market surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of devices.

9. A device is deemed to be "misbranded" under 21 U.S.C. § 352(t)(2) if a manufacturer fails or refuses to furnish any material information required by or under 21 U.S.C. § 360i respecting the device, including MDRs and supplemental MDRs. The FDCA prohibits the introduction of misbranded medical devices into interstate commerce, pursuant to 21 U.S.C. § 331(a).

Advocate Lutheran General Hospital

10. On or about June 25, 2013, PENTAX learned that four patients at Advocate Lutheran General Hospital in Chicago, Illinois, were infected with carbapenem-resistant Enterobacteriaceae after being treated with the same PENTAX duodenoscope. PENTAX later learned that more than 30 patients at that hospital were infected, including two patients who died, although the duodenoscope was not necessarily the cause of the infections and the infections were not necessarily the cause of death.

11. PENTAX was required to file MDRs about the infections of the four patients by July 25, 2013, but did not do so because the employees involved misunderstood the company's MDR-reporting responsibilities.

12. PENTAX filed an MDR about the infections at Advocate Lutheran General Hospital on or about September 20, 2013.

Massachusetts General Hospital

13. On about June 27, 2014, PENTAX learned that four patients at Massachusetts General Hospital in Boston, Massachusetts, were infected after being treated with the same PENTAX duodenoscope. PENTAX later learned that approximately 12 patients at that hospital were infected with Escherichia coli bacteria, none of whom died.

14. PENTAX was required to file MDRs about the infections of the four patients by July 27, 2014, but did not do so because the employees involved misunderstood the company's MDR-reporting responsibilities.

15. PENTAX filed an MDR about the infections at Massachusetts General Hospital on or about December 15, 2014.

16. PENTAX's gross profits from sales of the duodenoscope sales during the two months in 2013 and the four months in 2014 when the scope was misbranded were about $350,000.

Distribution of Endoscopes with Unapproved Instructions for Use

17. Because endoscopes are reusable devices, endoscopes must be cleaned – or "reprocessed" – after each use. If an endoscope is not cleaned properly, infectious material may remain on or in the endoscope, and subsequent patients treated with the endoscope may become infected, which may lead to serious illness or death.

18. The FDCA requires medical devices to bear adequate instructions for use. An endoscope's instructions for use include the reprocessing procedures established by the manufacturer.

19. A device is deemed to be "misbranded" under 21 U.S.C. § 352(f) if it bears inadequate instructions for use. As noted above, the FDCA prohibits the introduction of misbranded medical devices into interstate commerce, pursuant to 21 U.S.C. § 331(a).

20. In or around 2011, the FDA issued new guidance that called for manufacturers to make instructions for cleaning scopes more specific and more stringent.

21. In or around 2013, PENTAX submitted to the FDA revised IFUs for cleaning four of its endoscopes that were already being lawfully distributed in the United States. The four types of endoscopes included PENTAX's colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes, and will hereinafter be referred to as the "four scopes."

22. The FDA rejected the revised IFUs for the four scopes and said PENTAX either needed to (a) conduct additional testing to "validate" – *i.e.*, prove to the FDA – that the IFUs PENTAX had submitted would be effective in cleaning the scopes or (b) add additional steps to the instructions to meet worst-case scenarios.

23. PENTAX advised the FDA that it would meet the FDA's requirements by initially implementing the latter (adding steps to the cleaning instructions) while working to satisfy the FDA as to the former (conducting studies to try to validate the shorter set of cleaning instructions).

24. On or about April 9, 2014, the FDA approved revised PENTAX IFUs for the four scopes that contained additional cleaning steps. At that point, PENTAX was required to distribute these four scopes with the newly FDA-approved IFUs.

25. Instead, for the next 18 months, through September 2015, PENTAX shipped the four scopes with the old IFUs, not the new, more stringent, FDA-approved, now-required IFUs. PENTAX made a deliberate business decision to continue to use the older IFUs because it feared the additional cleaning steps required by the new IFUs would result in the loss of business. "Taking a manual cleaning process from 5 to 25 minutes is going to be catastrophic," one PENTAX employee wrote to another employee on April 4, 2014. Another internal email, on July 28, 2014, predicted the result of the new IFUs would be that customers "will be very upset and could switch away from PENTAX because of the extra time, labor, manpower, and cost to perform the new protocol."

26. In or around the end of September 2015, PENTAX began distributing two of the four types of scopes with the IFUs that the FDA had approved on or about April 9, 2014, and began distributing the other two types of scopes with new, shorter, validated cleaning instructions.

27. PENTAX's gross profits from sales of the four types of scopes from April 2014 to September 2015, when the scopes were misbranded, were about $18 million.

ATTACHMENT B

PENTAX OF AMERICA, INC.'S ADDITIONAL COMPLIANCE MEASURES AND REPORTING/CERTIFICATION OBLIGATIONS

With respect to all endoscope devices manufactured by Pentax of America, Inc., doing business as Pentax Medical Company and the HOYA Corporation, PENTAX Lifecare Division (collectively, "Pentax"), that are currently sold by Pentax in the United States, including, but not limited to, duodenoscopes, colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes, Pentax reports that it has instituted and shall maintain policies and procedures designed to prevent future violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") with respect to (a) medical device reporting ("MDR") and (b) endoscope instructions for use ("IFUs"), and Pentax agrees to do the following:

A. MDR Compliance Measures

Pentax agrees to continue to develop, establish, and maintain policies and procedures that comply with the MDR obligations, as prescribed by the FDCA and its implementing regulations (hereinafter "MDR Compliance Measures"), including, but not limited to, the following actions:

i. Implement and maintain adequate written MDR procedures in compliance with 21 C.F.R. Part 803 and ensure that employees are trained on, understand, and properly implement the MDR requirements and procedures; and

ii. Maintain accurate and complete complaint files and establish and implement adequate written procedures for receiving, reviewing, and evaluating complaints in compliance with 21 C.F.R. 820.198.

B. MDR Audit and Reporting

Within six (6) months of the Effective Date, Pentax shall inspect and review Pentax's then-current MDR policies and procedures, to determine if the current policies and procedures are in compliance with the MDR requirements of the FDCA and its implementing regulations (hereinafter the "MDR Audit") and shall submit simultaneously to the Offices and the U.S. Food and Drug Administration's ("FDA's") Center for Devices and Radiological Health ("CDRH") a complete written report of the MDR Audit (hereinafter "MDR Audit Report"), which shall include, but not necessarily be limited to:

i. Site-specific information (including each site's main function) identifying in detail which MDR policies and procedures (including SOPs and similar documents) Pentax reviewed and Pentax's evaluation as to whether each such policies and procedures are currently in compliance with the MDR requirements of the FDCA and its implementing regulations; and

ii. If applicable, listing any observed deviations from compliance with the FDCA provisions, and its implementing regulations, governing MDR (hereinafter "MDR Deviations"), categorized and organized as site-specific, regional, or corporate-wide MDR Deviations.

In the event the MDR Audit Report identifies MDR Deviations, within thirty (30) days after submitting the MDR Audit Report, Pentax shall submit a written report to FDA-CDRH detailing the specific actions Pentax has taken and/or shall take to address the MDR Deviations (hereinafter "MDR Work Plan"), including, if applicable, whether such corrective actions addressed and/or will address site-specific, regional, or corporate-wide MDR Deviations. In

addition, if the MDR Audit Report identifies any MDR reportable events that have not yet been reported to FDA, Pentax will submit an MDR to FDA-CDRH within 30 days.

As the actions detailed in the MDR Work Plan are completed, Pentax shall notify FDA-CDRH in writing, and following such notification, Pentax shall promptly inspect and verify whether those actions have been completed in a manner that complies with the MDR requirements of the FDCA and its implementing regulations. When Pentax determines that all of the actions identified in the MDR Work Plan have been completed to its satisfaction, Pentax shall provide simultaneously to the Offices and FDA-CDRH a written certification that all of the MDR Deviations have been corrected and that, based on Pentax's inspection(s) and review(s), Pentax's policies and procedures are in compliance with the MDR requirements of the FDCA and its implementing regulations (hereinafter "Pentax's Completion Certification"). Pentax's Completion Certification shall include a report of the results of Pentax's inspection(s) and review(s).

C. MDR Review

Following submission of Pentax's Completion Certification, Pentax shall conduct a review of Pentax's then-current MDR Compliance Measures to determine and ensure continued compliance with the MDR requirements of the FDCA and its implementing regulations (hereinafter the "MDR Review"), which should include a review of a statistically valid sample of MDR records, including MDRs related to all endoscopes manufactured by Pentax (including but not limited to MDRs of duodenoscopes, colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes), from the same time period as the MDR Review. Pentax shall report the results of each MDR Review to the Offices and FDA-CDRH. The report should identify in detail which MDR policies, procedures, and records Pentax reviewed and state Pentax's

evaluation as to whether such policies, procedures, and/or records currently are in compliance with the MDR requirements of the FDCA and its implementing regulations.

The first MDR Review period shall cover the one-year period following the date of Pentax's Completion Certification, and the report shall be submitted to the Offices and FDA-CDRH no later than fifteen (15) months after submission of Pentax's Completion Certification. The second MDR Review period shall cover the thirteenth (13th) through twenty-fourth (24th) months after submission of the Pentax's Completion Certification, and the report shall be submitted to the Offices and FDA-CDRH no later than twenty-seven (27) months after submission of the Pentax's Completion Certification.

Pentax's reports under Section (C) of this Attachment B will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation and undermine the objectives of the Compliance Measures. For these reasons, among others, the reports and their contents are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent that the Offices determine in their sole discretion that disclosure would be in furtherance of the Offices' discharge of their duties and responsibilities or is otherwise required by law.

D. Endoscopic IFU Reviews/Audits and Reporting

Pentax shall conduct a review and audit of all current IFUs distributed with, or otherwise accompanying, all endoscope devices manufactured by Pentax (not including accessories or surgical tools) that are currently sold by Pentax in the United States to ensure that all endoscope devices are being distributed with the FDA-approved or FDA-cleared IFUs, respectively (hereinafter the "IFU Review"). This IFU Review shall include review of Pentax's relevant

systems, processes, policies, and procedures for labeling controls relating to IFUs for endoscope devices.

The first IFU Review shall be conducted within six (6) months of the Effective Date and shall cover the time period from April 1, 2014, to the Effective Date. Pentax shall submit a report to the Offices and FDA-CDRH regarding the first IFU Review within six (6) months after the Effective Date. The second IFU Review shall cover the period from the Effective Date through twelve (12) months following the date of Pentax's Completion Certification, and the report shall be submitted to the Offices and FDA-CDRH no later than fifteen (15) months after submission of Pentax's Completion Certification. The third IFU Review period shall cover the thirteenth (13th) through twenty-fourth (24th) months after submission of Pentax's Completion Certification, and the report shall be submitted to the Offices and FDA-CDRH no later than twenty-seven (27) months after submission of Pentax's Completion Certification.

In the event any IFU Review identifies deviations ("IFU Deviations"), within thirty (30) days after submitting the respective report for such IFU Review, Pentax shall submit a written report to FDA-CDRH detailing the specific actions Pentax has taken and/or shall take to address the IFU Deviations. In addition, if any IFU Review identifies any devices distributed without the correct IFU, Pentax will send out the correct IFU within 15 days and provide additional training if needed.

The reports described in this Section will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation and undermine the objectives of the Compliance Measures. For these reasons, among others, the reports and their contents are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent

that the Offices determine in their sole discretion that disclosure would be in furtherance of the Offices' discharge of their duties and responsibilities or is otherwise required by law.