

K093677



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Endoscopy

Device Name

Proprietary Name: Stryker Arthroscope
 Common and Usual Names: Stryker Arthroscope
 Classification Name: Arthroscope (21 CFR § 888.1100, Product Code HRX)

Intended Use: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

Device Description: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. The Stryker Arthroscope is a long tube containing a series of lenses. At the distal end, an objective lens captures the image of the object. Lens along the rod relay the image. At the proximal end, a proximal coupling lens relays the image to a CCD (Camera).

The Stryker Arthroscopes come in various diameters including 1.9mm, 2.3mm, 2.7mm, and 4.0mm. Larger size arthroscopes are used for general viewing, while smaller diameter arthroscopes are used for restricted surgical sites. The Stryker Arthroscopes come in several directions of view including, 0°, 30°, 45°, 70°. The direction of view enables viewing of different parts. Materials of the Arthroscope include stainless steel, titanium, PEEK, Glass, and Sapphire.

Technological Characteristics: The Stryker Arthroscopes are substantially equivalent in construction and materials to the predicate Henke Sass Wolf Arthroscopes (K080560).

	Proposed Device	Predicate Device	Equivalence	Impact on Safety and Effectiveness
Device	Stryker Arthroscope	HSW Arthroscope		
Technological Characteristics (Design)				
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°	Different	The differences in the Field of view do not affect the safety and efficacy of the device.
Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°	Same	N/A

Outer Diameter	4mm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm	Same	N/A
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm	Different	The lengths are within the range of the predicate. The differences in the length do not affect the safety and efficacy of the device.
Single Use or Reusable	Reusable	Reusable	Same	Equivalent
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics	Same	N/A

Voluntary Safety and Performance Standards: The Stryker Arthroscopes conform to the voluntary standards including but not limited to (Refer to **Section 5.1**):

Biological Evaluation of Medical Devices

10993-1: Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing

10993-10: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

Electrical Safety Requirements Per 60601

IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-2-18: Medical Electrical Equipment - Part 2: Particular Requirements for the safety of endoscopic equipment

AAMI/ISO Standards for Sterilization of Medical Devices

TIR 12: Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities

ISO 14937: Sterilization of Health Care Products - General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices

Optics

ISO 8600-1: Optics and photonics — Medical endoscopes and endotherapy devices — Part 1: General requirements

ISO 8600-3: Optics and optical instruments: Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics

ISO 8600-5: Optics and photonics-Medical Endoscopes and Endoscopic Accessories-Part 5: Determination of Optical Resolution of rigid endoscopes with optics.

Performance Testing: The subject device has been subjected to and passed electrical safety, sterilization, and biocompatibility testing requirements. The patient contacting materials are identical to the materials used in the predicated device (Henke Sass Wolf Arthroscope K080560). The Stryker Arthroscopes met all specified design and performance requirements.

Predicate Devices: The Stryker Arthroscopes are substantially equivalent in terms of safety and effectiveness to the currently marketed device, Henke Sass Wolf Arthroscopes (K080560).

Substantial Equivalence: The technological differences between the Stryker Arthroscope and Henke Sass Wolf Arthroscopes do not raise new questions of safety or effectiveness. Therefore the Stryker Arthroscopes are substantially equivalent to the previously cleared Henke Sass Wolf Arthroscope (K080560). Refer to Section 7.0 for a detailed comparison.

Contact:



Feb 25, 2010

Date:

Shibir Desai

Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
Phone: 408-754-2784
Fax: 408-754-2521
Email: Shibir.Desai@stryker.com



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Stryker Endoscopy
% Shibir Desai
Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95136

MAR - 5 2010

Re: K093677
Trade/Device Name: Stryker Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: February 25, 2010
Received: March 2, 2010

Dear Shibir Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

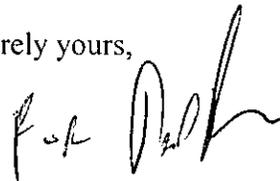
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE

Device Name: Stryker Arthroscope

510(k) Number if known: K093677

Stryker **Arthroscopes** are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

No known contraindications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael J. Finn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093677



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Stryker Endoscopy
% Shibir Desai
Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95136

MAR - 5 2010

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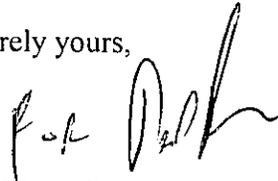
Page 2 - Shibir Desai

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Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number if known: K093677

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AND/OR Over-The-Counter Use _____
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093677



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 26, 2010

STRYKER ENDOSCOPY
ENDOSCOPY DIVISION
5900 OPTICAL CT.
SAN JOSE, CALIFORNIA 95138
UNITED STATES
ATTN: SHIBIR DESAI

510k Number: K093677

Product: STRYKER ARTHROSCOPE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 12, 2010

STRYKER ENDOSCOPY
ENDOSCOPY DIVISION
5900 OPTICAL CT.
SAN JOSE, CALIFORNIA 95138
UNITED STATES
ATTN: SHIBIR DESAI

510k Number: K093677

Product: STRYKER ARTHROSCOPE

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If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 01, 2009

STRYKER ENDOSCOPY
ENDOSCOPY DIVISION
5900 OPTICAL CT.
SAN JOSE, CALIFORNIA 95138
UNITED STATES
ATTN: SHIBIR DESAI

510k Number: K093677
Received: 11/27/2009
Product: STRYKER ARTHROSCOPE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Write the Payment Identification number on your check.
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A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/cover sheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) STRYKER ENDOSCOPY 5900 Optical Court San Jose CA 95138 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) Trade Secret	2. CONTACT NAME Shibir Desai 2.1 E-MAIL ADDRESS Shibir.desai@stryker.com 2.2 TELEPHONE NUMBER (include Area code) 408-754-2540 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
---	---

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) Trade Secret

13-Nov-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

1-31

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
 OMB No. 0910-0120
 Expiration Date: August 31, 2010.
 See OMB Statement on page 5.

Date of Submission: November 8, 2009
 User Fee Payment ID Number: (b)(4) Trade
 FDA Submission Document Number (if known):

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Stryker Corporation		Establishment Registration Number (if known) 2936485	
Division Name (if applicable) Endoscopy		Phone Number (including area code) 408-754-2540	
Street Address 5900 Optical Court		FAX Number (including area code) 408-754-2521	
City San Jose	State / Province CA	ZIP/Postal Code 95138	Country US
Contact Name Shibir Desai			
Contact Title Regulatory Affairs Analyst		Contact E-mail Address Shibir.Desai@Stryker.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

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SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2

REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (specify):		

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input checked="" type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1 HRX	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed (if known)

#	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K080560	1 Henke Sass Wolf Arthroscope	1 Henke Sass Wolf
2		2	2
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Stryker Arthroscope

#	Trade or Proprietary or Model Name for This Device	Model Number
1	Stryker Arthroscope	1 N/A
2		2
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1 K771200	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code HRX	C.F.R. Section (if applicable) 888.1100	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Arthroscope		

Indications (from labeling)

The Stryker Arthroscope and Accessories is an endoscopic device with accessory devices which attach to the Arthroscope and is intended to examine and/or perform surgery on the interior of a joint. Arthroscopic minimally invasive procedures are performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal-mandibular joint, ankle, elbow and feet (plantar fascia release).

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeier	
Company / Institution Name Stryker Corporation		Establishment Registration Number 2936485	
Division Name (if applicable) Endoscopy		Phone Number (including area code) 408-754-2540	
Street Address 5900 Optical Court		FAX Number (including area code) 408-754-2124	
City San Jose		State / Province CA	ZIP Code 95138
		Country U.S	
Contact Name Shibir Desai	Contact Title Regulatory Affairs Analyst	Contact E-mail Address Shibir.Desai@Stryker.com	

(b)(4) Trade Secret Process

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeier	
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code
		Country	
Contact Name	Contact Title	Contact E-mail Address	

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SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 8600-3	International Organization for Standardization	Optics and optical instruments Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics	First Edition	12/01/2003
2	IEC 60601-1:2005	International Electrotechnical Commission	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Third Edition	12/01/2005
3	IEC 60601-2-18	International Electrotechnical Commission	Medical Electrical Equipment - Part 2: Particular Requirements for the safety of endoscopic equipment	Second Edition	08/01/1996
4	ISO 8600-5	International Organization for Standardization	Optics and Optical Instruments-Medical Endoscopes and Endoscopic Accessories-Part 5: Determination of Optical Resolution of rigid endoscopes with optics.	First Edition	01/01/2005
5	ANSI/AAMI/ISO 14937	International Organization for Standardization	Sterilization of Health Care Products - General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	First Edition	12/15/2000
6	AAMI TIR 12	AAMI	Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	First Edition	12/23/2004
7	ISO 8600-1	International Organization for Standardization	Optics and photonics — Medical endoscopes and endotherapy devices — Part 1: General requirements	second edition	01/05/2005

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE: ANSI/AAMI/ISO 14937 - Sterilization of medical devices - General requirements for characterization of sterilizing agent and the development, validation, and routine control of a sterilization process: 2000

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 14-88

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: Updated 510(k) Sterility Review Guidance K90-1

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE *ANSI/AAMI/ISO 14937 - Sterilization of medical devices - General requirements for characterization of sterilizing agent and the development, validation, and routine control of a sterilization process.*

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER ALL	SECTION TITLE <i>General requirements for characterization of sterilizing agent and the development, validation, and routine control of a sterilization process.</i>	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹ AAMI TR12 - Designing, testing, and labeling reusable medical devices reprocessing in health care facilities: A guide for medical device manufacturers.

Please answer the following questions

Yes No

Is this standard recognized by FDA²? Yes No

FDA Recognition number³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS? Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard? Yes No
If yes, was the guidance document followed in preparation of this 510(k)? Yes No

Title of guidance: Updated 510(k) Sterility Review Guidance K90-1

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE <i>Designing, testing, and labeling reusable medical devices reprocessing in health care facilities</i>		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER ALL	SECTION TITLE <i>Designing, testing, and labeling reusable medical devices reprocessing in health care facilities</i>	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "Justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 8600-1 Optics and photonics-Medical endoscopes and endotherapy devices-Part 1:General requirements: 2005

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 9-37

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
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Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 8600-1 Optics and photonics-Medical endoscopes and endotherapy devices-Part 1:General requirements: 2005

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

1

SECTION TITLE

General Requirements

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 8600-3 Optics and optical instruments Medical endoscopes and endoscopic accessories :1997 Amendment 1:2003

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 9-38

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] (numeric identifier) [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 8600-3 Optics and optical instruments Medical endoscopes and endoscopic accessories:1997 Amendment 1:2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Determination of field of view and directio of view of endoscopes with optics	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 8600-5 Optics and photonics Medical endoscopes and endotherapy devices:2005

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 9-39

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] (numeric identifier) [title of standard] [date of publication]
² Authority (21 U.S.C. 360d), www.fda.gov/cdrh/stdsprog.html
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 8600-5 Optics and photonics Medical endoscopes and endotherapy devices:2005

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Determination of optical resolution of rigid endoscopes with optics	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC60601-1: General requirements for safety

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 5-4

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does this standard include acceptance criteria?
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	General requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

3.6, 3.7, 3.8, 3.9 do not apply.

DESCRIPTION

N/A

JUSTIFICATION

Not apply as the standard is for specific requirements which our device does not have.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Classification	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

5.1 does not apply

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not electrically powered.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Classification	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

5.5, 5.6 do not apply

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not electrically powered.

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STANDARD TITLE
IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Identification, marking and documentation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

6.2, 6.3, 6.4, 6.5, 6.6, 6.7 do not apply.

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device has no medical gas and connections, no indicator lights, no push-buttons for caution/emergency use.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Environmental conditions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

10.2.2

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not electrically powered and has no internal power.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
14	Requirements related to classification	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not electrically powered and has no power supply.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15	Limitation of voltage and/or energy	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is not electrically powered.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16	Enclosure and Protective covers	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is not electrically powered and is not a lamp holder.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
17	Separation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
17.a

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is part of the applied part but is not depended upon for isolation.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
17	Limitation of voltage and/or energy	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

17.d, e, f, g, h

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is only an accessory and not electrically powered.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
18	Protective earthing, functional earthing and potential equalization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

18.1-1

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is only an accessory and not electrically powered.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
19	Continuous leakage currents and patient auxiliary currents	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not an electrical device and does not contribute any leakage current.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
20	Dielectric strength	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is not an electrical device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21	Mechanical strength	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply per IEC60601-2-18

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
22	Moving parts	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is only an accessory, has no moving part.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
25	Expelled parts	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is not electrically powered, no display vacuum tubes either.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
28	Suspended masses	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as there is no suspension system with/without safety device for our device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
29	X-Radiation	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is not intended to produce X-Radiation.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
37, 38, 39, 40, 41	Protection against hazards of ignition of flammable anaesthetic mixtures	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not a flammable anaesthetic mixture.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, etc.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

44.2, 44.3, 44.4, 44.6

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device does not contain a liquid reservoir; there is no electrical property on our device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
45	Pressure vessels and parts subject to pressure	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device has no pressure vessels and not intended to use for pressure release.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
49	Interruption of the power supply	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not electrically powered.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
51	Protection against hazardous output	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device does not protect against hazardous outputs, not exceed safety limits.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
52	Abnormal operation and fault conditions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not electrically powered, and not applicable for single fault conditions.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
56	Components and general assembly	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not electrically powered.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
57	Main parts, components and layout	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is only an accessory and has no electrical properties.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
58	Protective earthing - Terminals and connections	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is only an accessory and has no electrical properties.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC60601-1: General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
59	Construction and layout	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device has no electrical properties, has no oil containers.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-2-18 Medical electrical equipment- particular requirements for the safety of endoscopic equipment

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 4-122

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-2-18 Medical electrical equipment- particular requirements for the safety of endoscopic equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	General requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

3.102, 3.103 do not apply

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not ultrasonic device, and does not provide a plurality of functions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Identification, marking and documents	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

6.8.2 aa)-5,6 do not apply

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device has no lamp, no gas embolism.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Identification, marking and documents	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

6.8.2.bb) does not apply

DESCRIPTION

N/A

JUSTIFICATION

Not apply as our device is not a High frequency surgical equipment.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-2-18 Medical electrical equipment- particular requirements for the safety of endoscopic equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 20	SECTION TITLE Dielectric Strength	CONFORMANCE? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
----------------------	--------------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device has no electrical properties.

SECTION NUMBER 36	SECTION TITLE Electromagnetic compatibility	CONFORMANCE? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
----------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device has no electrical properties.

SECTION NUMBER 42	SECTION TITLE Excessive temperatures	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED *
42.5 Guards

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device has no lamp.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-2-18 Medical electrical equipment- particular requirements for the safety of endoscopic equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
42	Excessive temperatures	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
42.101 Thermal hazards for High frequency surgical equipment

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is not a high frequency equipment.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
56	Components and general assembly	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
56.3c

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device is a endoscope.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
57	Main parts, Components and layout	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
Not apply as our device has no electrical properties.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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285

5900 Optical Court
San Jose, CA 95138
t: 408 754 2000 f: 408 754 2521

K093677
stryker[®]

Endoscopy

November 25, 2009

FDA CDRH DMC

NOV 27 2009

Food and Drug Administration
Center for Devices and Radiology Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Received

K-31

Re: Stryker Endoscopy (FDA Registration # 2936485) - Traditional 510(k) Pre-Market Notification for Stryker Arthroscopes

Dear Sir or Madam:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, through this pre-market notification we are notifying the FDA of Stryker Endoscopy's intent to market the Stryker Arthroscopes.

The different sections and supporting documentation of this submission are organized as described by the table of contents. A separate summary of the safety and effectiveness is included. This submission will substantiate the safety and effectiveness of the Stryker Arthroscopes

If there are any questions regarding this 510(k) pre-market notification, please contact me by phone 408-754-2784 or email Shibir.Desai@Stryker.com.

Sincerely,



Shibir Desai
Regulatory Affairs Analyst
Stryker Endoscopy
San Jose, CA 95138

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Endoscopy

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APPENDIX 5: OPTICAL PERFORMANCE RESULTS

APPENDIX 6: STERRAD STERILIZATION REPORT

K093677

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

I certify that, in my capacity as a Regulatory Affairs Analyst of Stryker Endoscopy, I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been knowingly omitted.

By:



Date Nov 25, 2009

Shibir Desai
Regulatory Affairs Analyst
Stryker Endoscopy

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INTENDED USE

Device Name: Stryker Arthroscope

510(k) Number if known: K093671

Stryker **Arthroscopes** are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

No known contraindications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/1
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name K093677
Proprietary Name: Stryker Arthroscope
Common and Usual Names: Stryker Arthroscope
Classification Name: Arthroscope (21 CFR § 888.1100, Product Code HRX)

Device Description and Intended Use: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

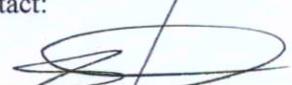
Voluntary Safety and Performance Standards: The Arthroscope will conform to the voluntary standards including but not limited to (Refer to **Section 5.1**):

- Biological Evaluation of Medical Devices
- Electrical Safety Requirements Per 60601
- AAMI/ISO Standards for Sterilization of Medical Devices
- ISO Standard for Optical Performance

Predicate Devices: The Stryker Arthroscopes are substantially equivalent in terms of safety and effectiveness to the currently marketed device, Henke Sass Wolf Arthroscopes (K080560).

Substantial Equivalence: The technological differences between the Stryker Arthroscopes and Henke Sass Wolf Arthroscopes do not raise new questions of safety or effectiveness. Therefore the Stryker Arthroscopes are substantially equivalent to the previously cleared Henke Sass Wolf Arthroscopes (K080560). Refer to Section 7.0 for a detailed comparison.

Contact:


Shibir Desai
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
Phone: 408-754-2784
Fax: 408-754-2521
Email: Shibir.Desai@stryker.com

Nov 25, 2009
Date:

1.0 **INTRODUCTION**

This traditional 510(k) submission letter is submitted to notify the FDA of Stryker Endoscopy's intent to market the Stryker Arthroscopes.

2.0 **DEVICE SPONSOR**

Stryker Endoscopy is the sponsor of this pre-market notification. Stryker Endoscopy has an established history of manufacturing and marketing medical products for orthopedic surgery.

Table 1

Sponsor of 510(k):	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 FDA Registration # 2936485
Owner:	Stryker Corporation 2725 Fairfield Road Kalamazoo, MI 49002 FDA Registration # 1811755
Manufacturer of Arthroscope	(b)(4) Trade Secret Process 
Correspondence Regarding this 510(k):	Shibir Desai Regulatory Affairs Analyst Stryker Endoscopy 5900 Optical Ct. San Jose, CA 95138 Phone : 408-754-2784 Fax : 408-754-2521 Email : Shibir.Desai@Stryker.com

3.0 DEVICE IDENTIFICATION

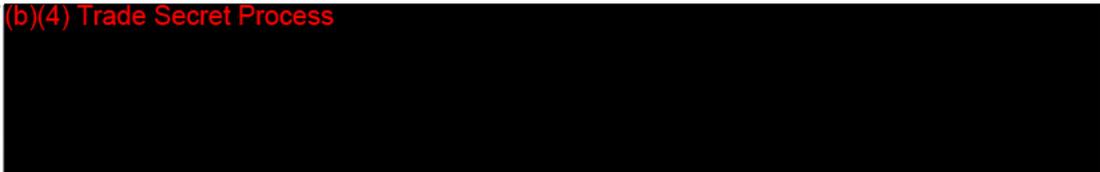
3.1 Proposed Device Name

Table 2

Proprietary Name:	Stryker Arthroscope
Common and Usual Name:	Stryker Arthroscope

3.2 Predicate Device Name

(b)(4) Trade Secret Process



4.0 CLASSIFICATION AND PRODUCT CODE

Table 4

Classification Name	Product Code	Product Class	Regulation Number
Arthroscope	HRX	II	888.1100

5.0 SECTION 514 SPECIAL CONTROLS

No performance standards or special controls have been established under section 514 of the Federal Food, Drug, and Cosmetic Act.

However, Stryker Endoscopy has chosen to comply with the following voluntary standards:

5.1 Voluntary Standards

The Stryker Arthroscope will conform to the voluntary standards including but not limited to:

Biological Evaluation of Medical Devices: 10993-1

Electrical Safety Requirements Per 60601: IEC 60601-1, IEC 60601-2-18

AAMI/ISO Standards for Sterilization of Medical Devices: TIR 12, ISO 14937

International Organization for Standardization: ISO 8600-1, ISO 8600-3, ISO 8600-5

6.0 DEVICE DESCRIPTION

6.1 Intended Use

Stryker **Arthroscopes** are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes

are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

6.2. System Description and Video System Diagram

(b)(4) Trade Secret Process

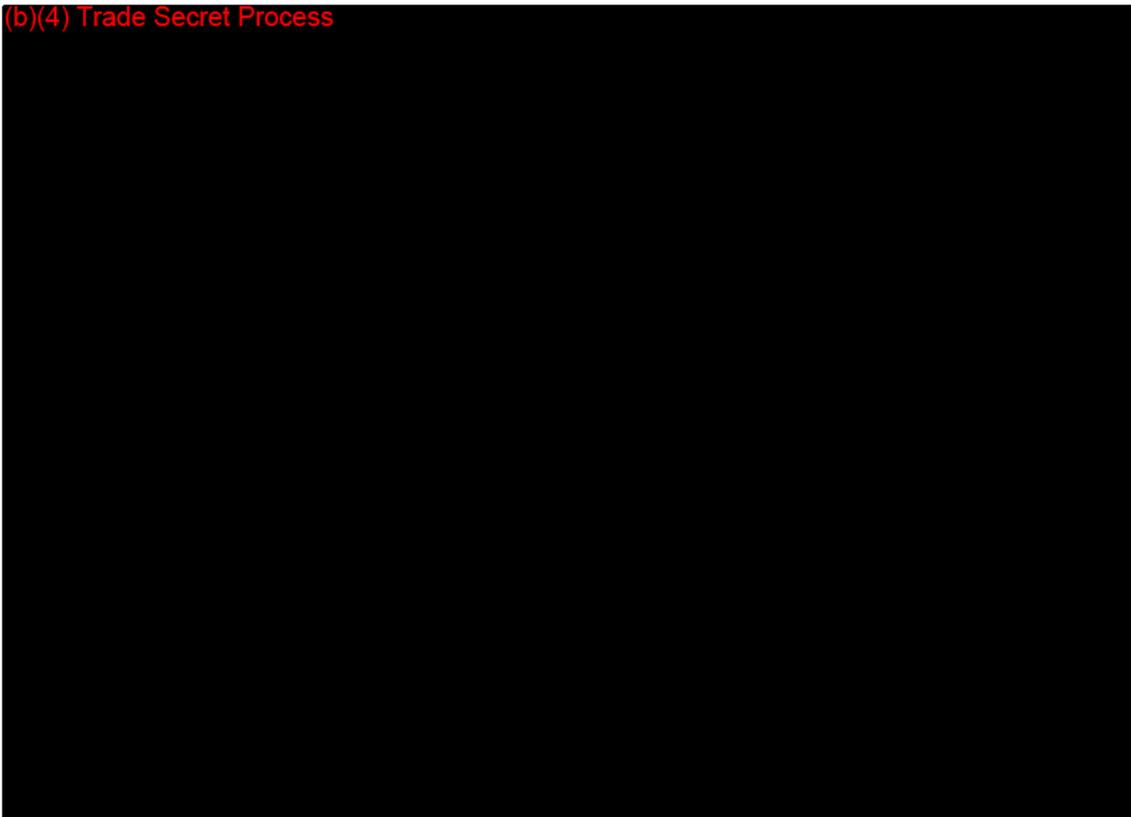
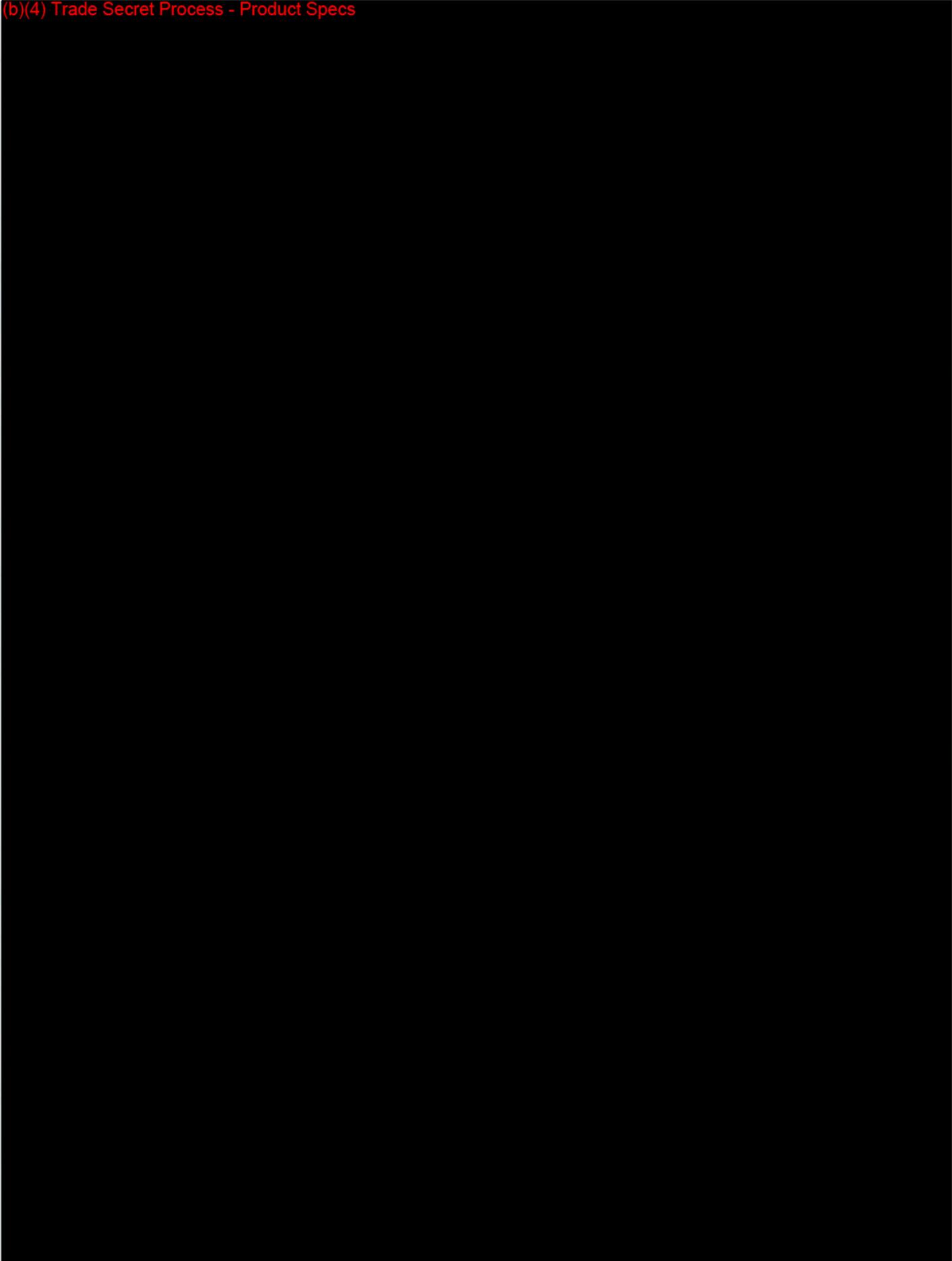


Table 1: Specifications of Arthroscopes

(b)(4) Trade Secret Process

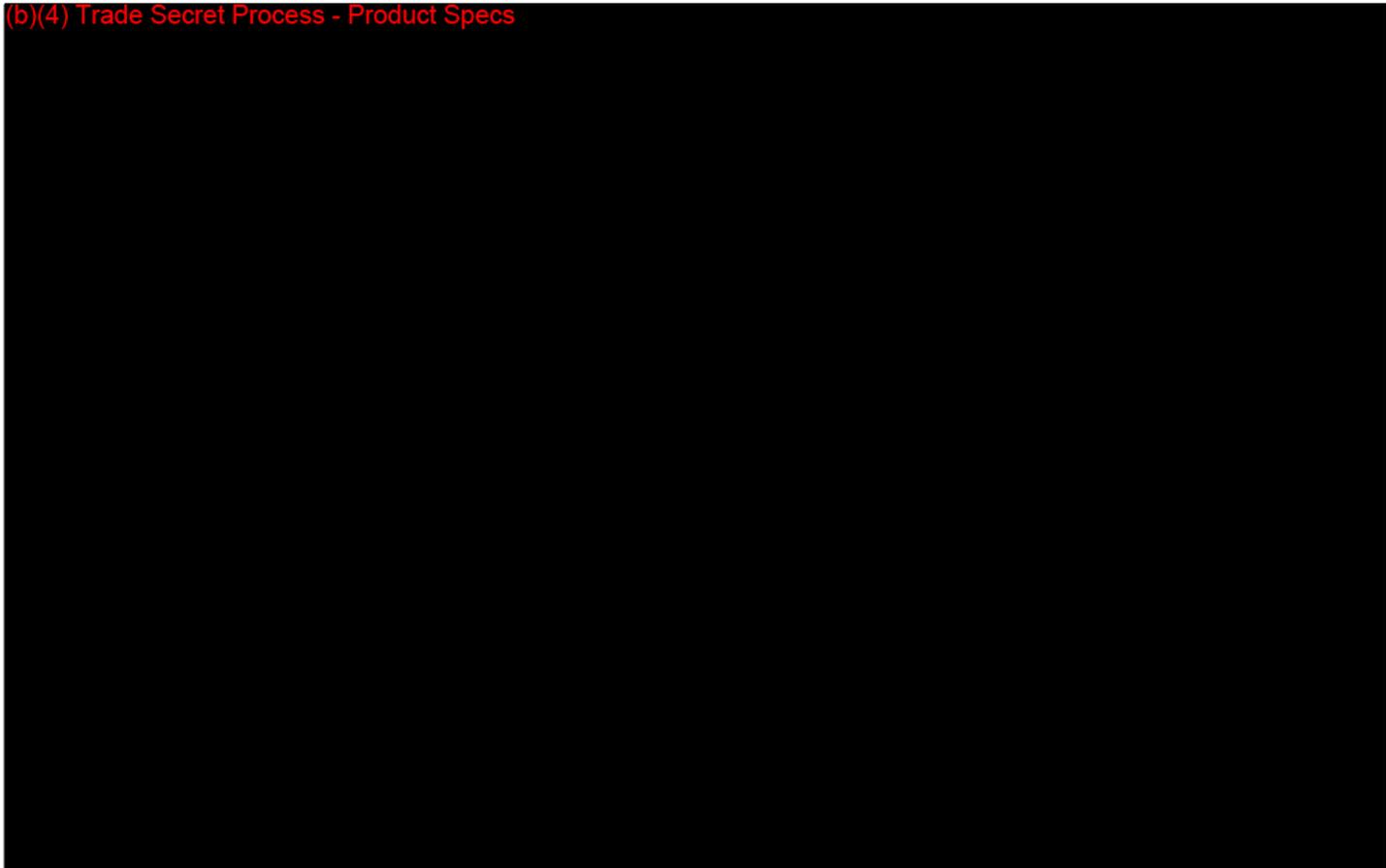


(b)(4) Trade Secret Process - Product Specs



6.3. Safety and Performance Testing

(b)(4) Trade Secret Process - Product Specs



6.3.2. Biocompatibility: (b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



6.3.3. Sterilization: (b)(4) Trade Secret Process - Product Specs



7.0 SUBSTANTIAL EQUIVALENCE COMPARISON

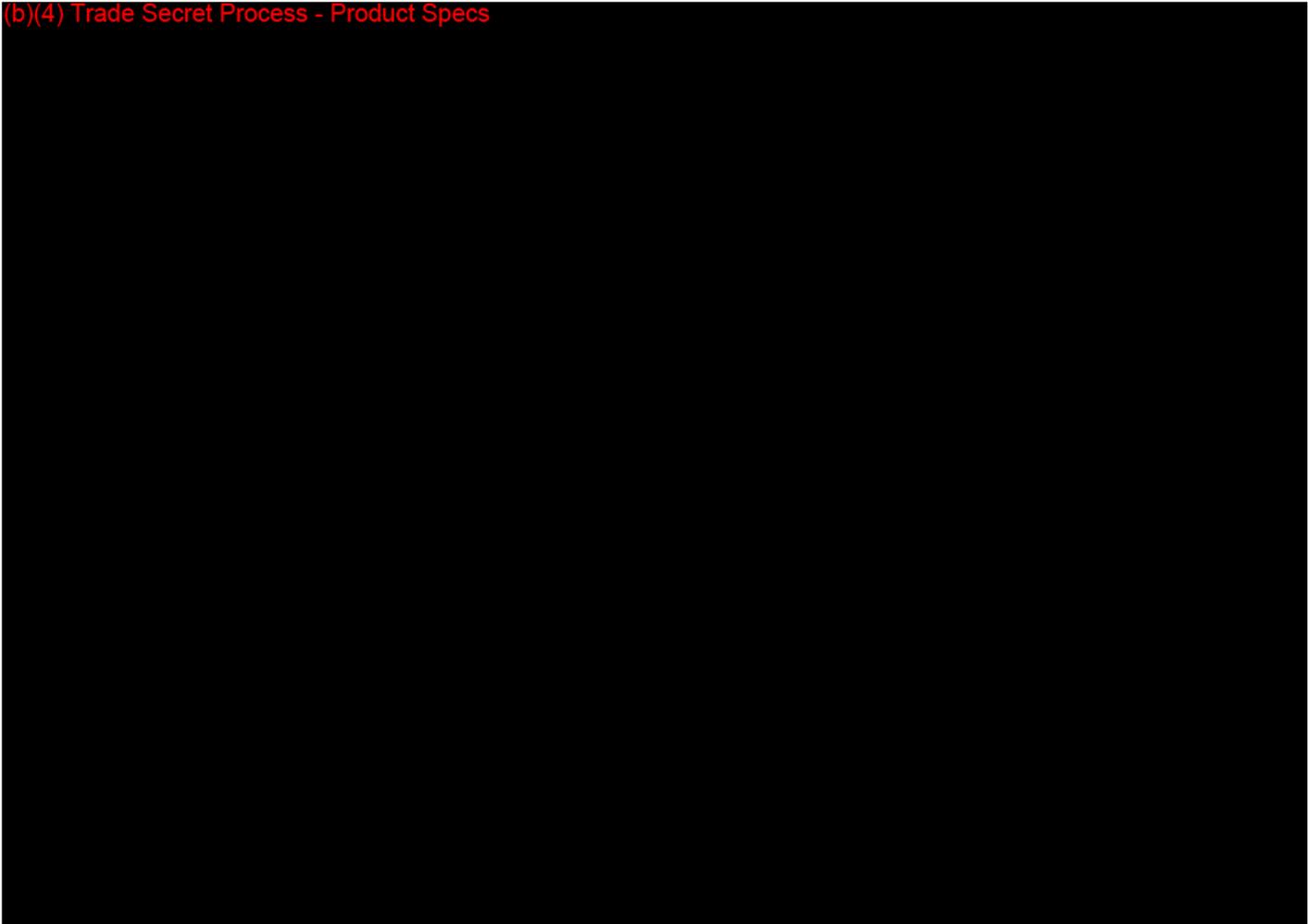
Substantial Equivalence

	Proposed Device	Predicate Device	Equivalence	Impact on Safety and Effectiveness
Device	Stryker Arthroscope	HSW Arthroscope		
Intended Use	Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).	The HSW Arthroscope and accessories is a tubular endoscopic device with accessory devices which attach to the Arthroscope and is intended to examine and / or perform surgery on the interior of a joint. Arthroscopic minimal invasive procedures are performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporalmandibular joint, ankle, elbow and feet (plantar fascia release).	Same	N/A
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°	Different	The differences in the Field of view do not affect the safety and efficacy of the device.

Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°	Same	N/A
Outer Diameter	4mm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm	Same	N/A
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm	Different	The lengths are within the range of the predicate. The differences in the length do not affect the safety and efficacy of the device.
Single Use or Reusable	Reusable	Reusable	Same	Equivalent
Sterilization Methods	(b)(4) Trade Secret Process - Product Specs			
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics	Same	N/A
Materials	(b)(4) Trade Secret Process - Product Specs			

2d7

(b)(4) Trade Secret Process - Product Specs

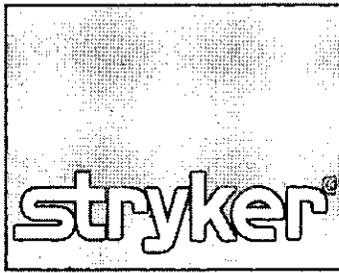


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APPENDIX 1

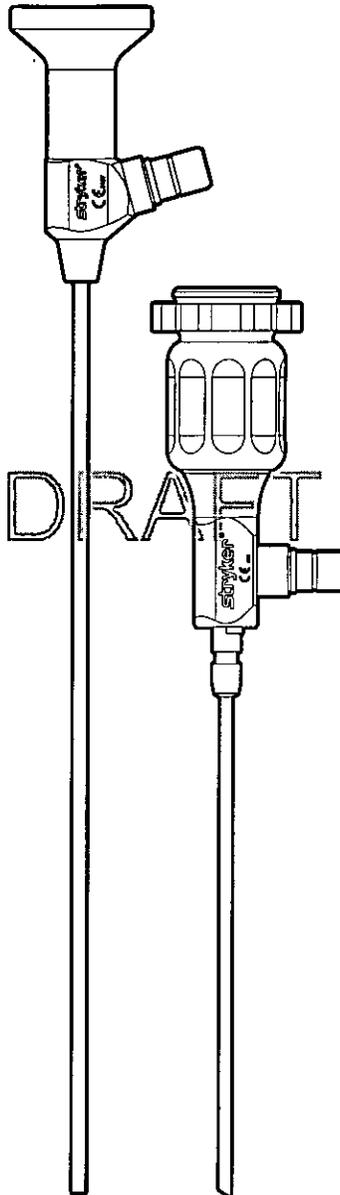
APPENDIX 2

APPENDIX 3



**Autoclavable
Arthroscopes**

CE₀₁₉₇ R_X ONLY



Indications for Use

Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal-mandibular joint, ankle, elbow, and feet (plantar fascia release).

Contraindications

None known.

Warnings

1. Federal law (USA) restricts this device to sale by or on the order of a physician.
2. This endoscope is shipped non-sterile. To prevent infection, this endoscope must be cleaned and sterilized by the user prior to use.
3. Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques. Consult medical literature relative to techniques, complications and hazards prior to performance of any endoscopic procedure.
4. Failure to use protective filters or suitable filtering spectacles during the activation of a surgical laser beam may cause eye damage to the user.
5. Temperatures near, and in front of the high intensity light emitting tip may cause permanent tissue damage and / or coagulation if brought into patient contact.
6. High intensity light may ignite drapes or similar material if the endoscope is left unattended when connected to a light source.
7. The surface temperature near the light cable inlet may exceed 41°C if the unit is operated at maximum brightness for extended periods of time. Prior to disconnecting light guides or light guide connectors, turn off the illumination source and allow the endoscope to cool.
8. Before each use, the outer portion of the endoscope intended to be inserted into the patient should be checked to ensure there are no rough edges or protrusions that may accidentally cut or damage patient tissue.
9. Contact with a rotating shaver or cutting instrument may cause the surface of the endoscope to become sharp or jagged or may result in portions of the endoscope being broken into the patient.
10. Failure to remove the endoscope and endoscopically-used accessories during a cardiac defibrillator discharge may lead to punctured or ripped patient tissue.

Cautions	
1.	Keep endoscope clean and dry when not in use. The stainless steel exterior of the endoscope is rust-resistant, not rust-proof.
2.	Bending the endoscope, or using the endoscope as a lever or pry bar, may result in lens damage and may render the scope unusable.
3.	Contact with a surgical laser beam may damage the endoscope surface and internal optics.

Electrical Safety

- Stryker endoscopes are classified as Type CF when attached to a Type CF applied part, and Type BF when attached to a Type BF applied part.
- When endoscopes are used with energized endoscopically-used accessories, patient leakage currents may be additive. To minimize total patient leakage current, use only Type CF or Type BF endoscopically-used accessories. Type CF applied parts should always be used together with other Type CF applied parts.
- If fluids, handling, or other devices bridge metal surfaces on both sides of insulating components, patient isolation may be defeated.
- Consult literature for the safe use of electrosurgical equipment.

Inadvertent burns can occur when the appropriate patient return path is obstructed.

Symbol Definitions



See instructions for use

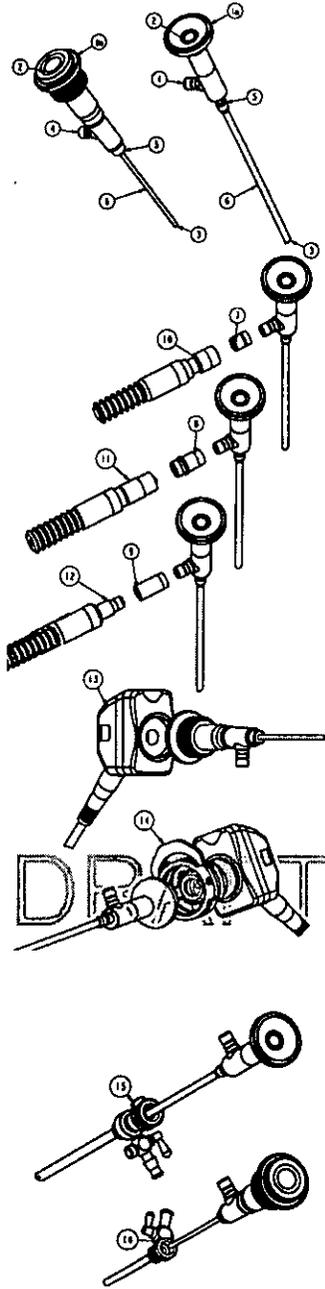


Relative humidity range



Ambient temperature range

**Instructions for Use /
Endoscope Parts**



- 1a. Eyepiece
- 1b. C-Mount Threads
- 2. Window
To ensure best image, clean with sterile alcohol wipes or cotton tip applicators and isopropyl alcohol.
- 3. Scope Tip
- 4. Light Cable Inlet
- 5. Endoscopic Hardware Locking Surface
- 6. Insertion Portion of Endoscope
- 7. Wolf Scope End Adapter (Included)
- 8. Storz Scope End Adapter (Included)
- 9. ACMI Scope End Adapter (Included)
Thread onto endoscope. Disassemble for cleaning / sterilization
- 10. Light Cable with Wolf Scope End (Sold separately)
Push onto / Pull off cable adapter. For

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best performance, ensure light cable is not worn or damaged

11. **Light Cable with Storz Scope End (Sold separately)**
Thread onto cable adapter. For best performance, ensure light cable is not worn or damaged.
12. **Light Cable with ACMI Scope End (Sold separately)**
Push onto / pull off cable adapter. For best performance, ensure light cable is not worn or damaged.
13. **C-Mount Camera Head (Sold separately)**
Thread tightly
14. **Camera Head / Focusing Coupler (Sold separately)**
15. **Speed-Lock™ Cannula (Sold separately)**
Slide endoscope into cannula until lock engages. Disassemble for cleaning / sterilization
16. **J-Lock Cannula (Sold separately)**
Rotate groove on endoscope against pin on cannula to lock. Disassemble for cleaning / sterilization

Reprocessing

These reprocessing instructions are provided in accordance with ISO 17664, AAMI TIR 12, and AAMI ST81. While they have been validated by Stryker as being capable of preparing the device for re-use, it remains the responsibility of the processor to ensure that the reprocessing, as actually performed (using equipment, materials, and personnel in the reprocessing facility), achieves the desired result. This normally requires validation and routine monitoring of the process. Stryker recommends users observe these standards when reprocessing medical devices.

Warnings

- This device must be cleaned and sterilized prior to the first use and after every subsequent use.
- Use only the sterilization cycles outlined in this document. Using unspecified sterilization cycles may damage the device or result in incomplete sterilization.
- Separate the camera head, coupler, and scope prior to cleaning, disinfection, or sterilization. If the coupler and scope are cleaned, disinfected, or sterilized as a single unit, disconnecting the devices during use will compromise the sterility of the two products. (Refer to the camera head and coupler product manuals for reprocessing instructions.)
- Wear appropriate protective equipment: gloves, eye protection, etc.

Cautions

- Do not use brushes or pads with metal or abrasive tips during manual cleaning, as permanent scoring or damage could result.
- To minimize galvanic corrosion, avoid soaking dissimilar metals in close proximity.
- Only scopes marked **AUTOCLAVABLE** can withstand steam sterilization. Autoclaving scopes that do not bear this marking will result in product damage.
- Allow the device to air cool following steam sterilization. Rapid cooling or "quenched" in a liquid will damage the device and void the warranty.

Limitations on Reprocessing

- Using multiple sterilization methods may significantly reduce the performance of the device and is not recommended. Autoclave is the preferred method.
- Proper processing has a minimal effect on this device. End of life is normally determined by wear and damage due to use.
- Damage incurred by improper processing will not be covered by the warranty.

Instructions

<p>Point of Use</p>	<p>Wipe excess soil from the device using disposable paper towels.</p> <ul style="list-style-type: none"> • If an automated reprocessing method will be used, rinse any channels in the device with 50mL of sterile distilled water immediately after use.
<p>Containment and Transportation</p>	<ul style="list-style-type: none"> • Reprocess the device as soon as reasonably practical following use. • Transport the device in a tray to avoid damage.
<p>Preparation for Cleaning</p>	<ol style="list-style-type: none"> 1. Disassemble the scope from the coupler and camera head. 2. Prepare an enzymatic detergent according to the manufacturer's recommendations (one ounce per gallon of tap water at 35 - 40°C). 3. Wipe the entire device with the detergent, using a clean cloth. 4. Immerse the device in the detergent. Inject any inside regions of the device with 50mL of the detergent solution to remove loose debris. 5. Soak the device in the detergent for at least 15 minutes.

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- 1. Brush**
- Thoroughly brush the exterior of the device with a soft-bristled brush, focusing on any mated or rough surfaces.
 - Inject any lumen or mated surface a minimum of five times with at least 50mL of the detergent.
 - Brush any lumens a minimum of five times from each end, using an appropriate bottle brush.
 - Brush any movable parts in their extreme open and closed positions.

- 2. Rinse**
- Rinse the device with treated water at ambient temperature to remove all detergent residue. Flush any lumens or mated surfaces a minimum of 5 times. Once all detergent residues have been removed, continue to rinse for a minimum of 30 seconds.
 - Drain excess water from the device and dry it using a clean cloth or pressurized air.
 - Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1 and 2.

- 3. Soak**
- Prepare a non-enzymatic detergent, according to the manufacturer's recommendations of 0.25 ounces/gallon tap water at 35 - 40°C.
 - Fully immerse the device and inject any lumens and mated surfaces with at least 50mL of the detergent.
 - Soak the device for a minimum of 15 minutes.

- 4. Brush**
- Thoroughly brush the exterior of the device using a soft-bristled brush.
 - Inject the prepared detergent into any cannulae, lumens, or mated surfaces a minimum of 5 times.
 - Brush any lumens a minimum of 5 times from each end, using an appropriate bottle brush.
 - Actuate the device, brushing around any movable parts in all extreme positions.

Automated Cleaning	<p>5. Rinse</p> <ul style="list-style-type: none"> Thoroughly rinse the device with treated water until all detergent residue is removed. Flush any lumens or crevices 5 times. After the detergent residue is removed, continue rinsing for a minimum of 30 seconds. Drain the excess water from the device and dry it with a clean cloth or pressurized air.
	<p>1. Brush</p> <ul style="list-style-type: none"> Brush both ends of any lumens a minimum of five times, using an appropriate bottle brush.
	<p>2. Rinse</p> <ul style="list-style-type: none"> Rinse the device with treated water at ambient temperature until there is no visible detergent residue. Continue to rinse for a minimum of 30 seconds after all detergent residue has been removed. Place the device in the washer on an incline to facilitate drainage.
	<p>3. Automated wash</p> <ul style="list-style-type: none"> Program the washer using the following parameters: <p style="text-align: center;"> DRAFT <small>If necessary, use pressurized air to aid in drying. Visually inspect each device for cleanliness.</small> </p>

	Recirculation Time	Water Temperature	Detergent Type and Concentration (if applicable)
Pre Wash	2 minutes	Cold	N/A
Enzyme Wash	2 minutes	Hot	Enzymatic Detergent
Wash 1	2 minutes	Set Point (66° C)	Regular Detergent
Rinse 1	2 minutes	Hot	N/A
Dry Phase	7 minutes	115° C	N/A

Disinfection (optional)	<ol style="list-style-type: none"> 1. Disinfect the device in a disinfecting solution that has the following active ingredient: $\geq 2.4\%$ glutaraldehyde (with minimum immersion time of 45 minutes at 25°C)* 2. Prepare the disinfecting solution according to the manufacturer's instructions. 3. Per manufacturer's recommendations, immerse the device in the disinfecting solution for the required time at the appropriate temperature, filling all lumens. 4. Using a syringe, flush any lumens and openings a minimum of 10 times each with the same disinfecting solution. 5. Thoroughly rinse and flush all interior and exterior surfaces with running deionized water until the device is visibly clean and all disinfecting solution and/or residue is removed. Dry all parts with a lint-free towel immediately after rinsing. <p>*Cidex* Activated Solution was validated for disinfection efficacy with an immersion time of 45 minutes at 25°C.</p>
Drying	<p>For automated drying, use the drying cycle provided with the washer/disinfector.</p> <ul style="list-style-type: none"> • For manual drying, use a lint-free cloth. • Dry any lumens with compressed air.
Maintenance, Inspection, and Testing	<ul style="list-style-type: none"> • Inspect the device on a continual basis. If a problem is observed or suspected, the device should be returned for repair. • Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and disinfection procedures.
Packaging	N/A

Sterilization			
After performing the cleaning instructions specified above, perform one of the following sterilization cycles.			
Ethylene Oxide (EtO)			
	Pre-conditioning	Sterilization	Aeration
Temperature	55°C (131 ± 5°F)	55 °C (131 ± 5°F)	51 - 59°C (124° - 138°F)
Relative Humidity	70% RH	70% RH	—
Vacuum Set Points	1.30 psia	—	—
EtO Concentration	—	725 mg/L	—
Time	30 minutes	1 hour	12 hours

Steam

- Steam sterilization is intended only for scopes marked autoclavable.
- Unwrapped "Flash" steam autoclave cycle is not recommended because water source impurities may cause hard films to build up on the outer optical windows of the endoscope which reduce optical performance.
- Rapid cooling, or "quenching," the endoscope after autoclaving will result in product damage.

	Gravity	Pre-vacuum	"Flash" Pre-vacuum
Wrapping	Double	Double	—
Temperature	132-137°C (270-279°F)	132-137°C (270-279°F)	132-137°C (270-279°F)
Time	10 minutes	3 minutes	3 minutes
Dry Time	50 minutes	50 minutes	—

⚠ Warning: Drying time depends on several variables, including: altitude, humidity, type of wrap, preconditioning, size of chamber, mass of load, material of load, and placement in chamber. Users must verify that drying time set in their autoclave yields dry surgical equipment.

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	<p>STERRAD*</p> <ol style="list-style-type: none"> 1. Clean and prepare the scope as recommended in the Cleaning and Disinfection sections. 2. Sterilize the scope using the STERRAD* 100S or STERRAD* NX Sterilization System. 3. Allow the scope to completely dry before reassembling it to a coupler or camera head. Otherwise, the lens will fog during use.
	<p>STERIS* System 1</p> <ol style="list-style-type: none"> 1. Disinfect the coupler using STERIS* System 1 with STERIS* Sterilant 20. 2. Allow the scope to completely dry before reassembling it to a coupler or camera head. Otherwise, the lens will fog during use.
Storage	N/A

**Environmental
Conditions for
Transport/Storage**

Observe the following environmental conditions for transport and storage:

- Temperature: -35° to 65°C
- Relative Humidity: 10% to 80%

DRAFT
Endoscope Disposal

Endoscopes must be disposed of according to local laws and hospital practices. The device does not contain any hazardous materials.

DRAFT

Speed-Lock™ and IDEAL EYES™ are trademarks of Stryker Corporation

STERIS® and System 1® are registered trademarks of STERIS Corporation.

STERRAD® and Cidex® are registered trademarks and NX® is a trademark of ADVANCED STERILIZATION PRODUCTS, Division of Ethicon Inc., a Johnson & Johnson company



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Stryker European Representative
Regulatory Manager, Stryker France
ZAC Satolas Green Pusignan
Av. de Satolas Green
69881 MEYZIEU Cedex, France

P11785A
2009/11

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APPENDIX 4

APPENDIX 5

APPENDIX 6



COVER SHEET MEMORANDUM

From: Reviewer Name Michel Janda
Subject: 510(k) Number K093677/52
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary (510(k) Statement)	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <= 21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days - < 2 years old)			X
Child (2 years - < 12 years old)			X
Adolescent (12 years - < 18 years old)			X
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing; different protocol procedures, etc.)			X

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old) X
Nanotechnology X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) X Contact OC.

Regulation Number 888.1100 Class II Product Code HRX

Additional Product Codes: _____ (If unclassified, see 510(k) Staff)

Review: Neil R. P. Ogdan GSDB 3/5/10
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 3/5/2010
(Division Director) (Date)



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue, WO66
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional/Abbreviated
K093677

Date: 3/04/10
To: The Record
From: Michel Janda, Biomedical Engineer

Office: ODE
Division: DSORD/GSDB

510(k) Holder: Stryker Endoscopy
5900 Optical Ct.
San Jose, CA 95138

Device Name: Stryker Arthroscope

Contact: Shibir Desai, Regulatory Affairs Analyst
Phone: (408) 754-2784 Fax: (408) 754-2521
Email: Shibir.Desai@Stryker.com

Handwritten signature and date: NY PAM 3/5/10

I. Purpose and Submission Summary:

The sponsor has submitted K093677 to notify the FDA of their intent to introduce the Stryker Arthroscope into interstate commerce.

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include: Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, Standards Form.

III. Device Description

Table with 4 columns: Question, Yes, No, N/A. Rows include: Is the device life-supporting or life sustaining?, Is the device an implant (implanted longer than 30 days)?, Does the device design use software?, Is the device sterile?, Is the device reusable (not reprocessed single use)?, Are "cleaning" instructions included for the end user?



III. Indications for Use

The Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

The subject device's indications for use is equivalent to that cleared within K080560.

IV. Predicate Device Comparison

Henke Sass Wolf of America Arthroscope (K080560) –

Indications for use: The HSW Arthroscope and accessories is a tubular endoscopic device with accessory devices which attach to the Arthroscope and is intended to examine and / or perform surgery on the interior of a joint. Arthroscopic minimal invasive procedures are performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal-mandibular joint, ankle, elbow and feet (plantar fascia release).

	Stryker Arthroscope (Subject Device)	HSW Arthroscope
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°
Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°
Outer Diameter	4mm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm
Single Use or Reusable	Reusable	Reusable
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics

V. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.807.87 (e). Draft primary labeling is provided in Attachment 1. Instructions for use are provided in Attachment 3.

VI. Sterilization/Shelf Life/Reuse

(b)(4) Trade Secret Process - Product Specs



VII. Biocompatibility

(b)(4) Trade Secret Process - Product Specs



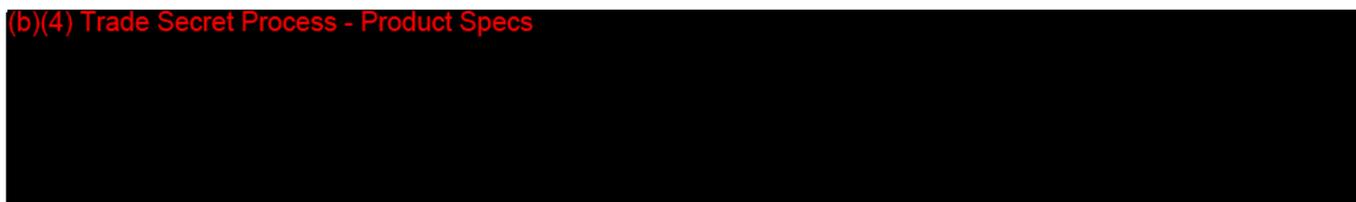
VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

(b)(4) Trade Secret Process - Product Specs



IX. Voluntary Standards

(b)(4) Trade Secret Process - Product Specs



STANDARD NUMBER	DATE	STANDARD TITLE
<i>Electrical Safety:</i>		
IEC 60601-1	2005	Medical Electrical Equipment. Part 1: General Requirements for Safety
IEC 60601-2-18	1996	Medical Electrical Equipment – Part 2 Particular Requirements for the safety of endoscopic equipment.
<i>Optics:</i>		
ISO 8600-1	2005	Optics and photonics – Medical endoscopes and endotherapy devices – Part 1: General Requirements.
ISO 8600-3	2003	Optics and optical instruments: Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics.
ISO 8600-5	2005	Optics and optical instruments: Medical endoscopes and endoscopic accessories Part 5: Determination of Optical Resolution of rigid endoscopes with optics.
<i>Sterilization:</i>		
ISO 14937	2000	Sterilization of Health Care Products – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation , and Routing Control of a Sterilization Process for Medical Devices.
AAMI TIR 12	2004	Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities.
<i>Biological Evaluation:</i>		
ISO 10993-1	2003	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
ISO 10993-10	2003	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

X. Performance Testing – Bench

The sponsor has provided the results of optical performance testing results within Appendix 5.

XI. Performance Testing – Animal

Not applicable.

XII. Performance Testing – Clinical

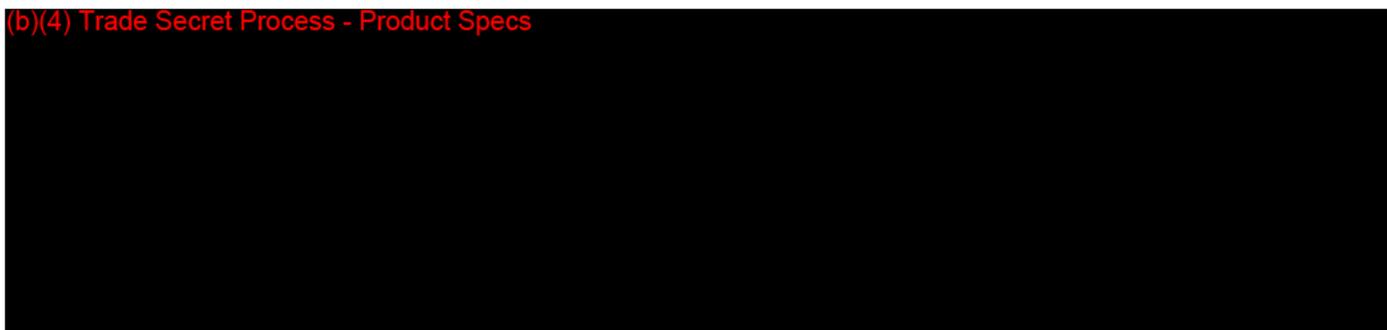
Not applicable.

XIII. Substantial Equivalence Discussion

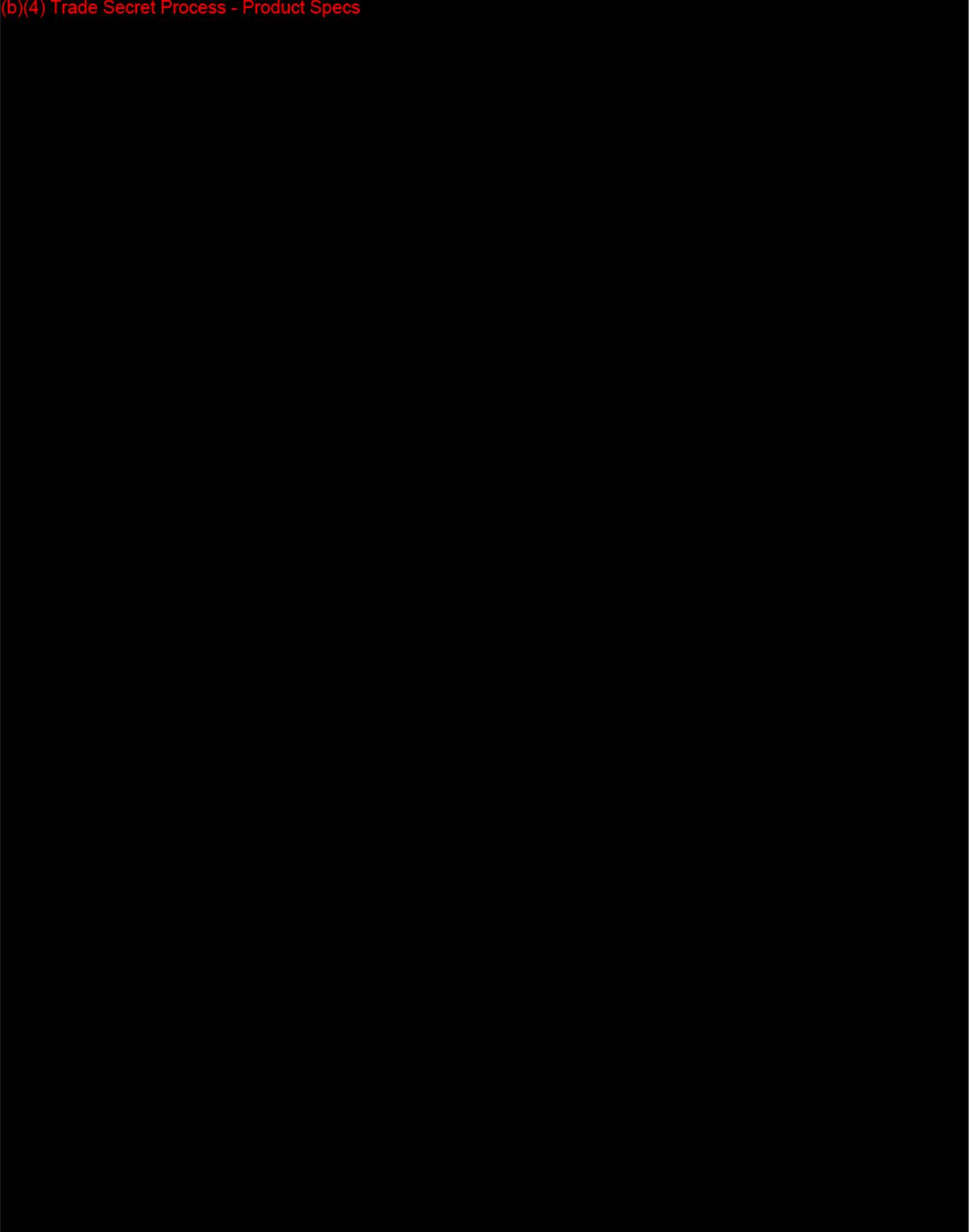
	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

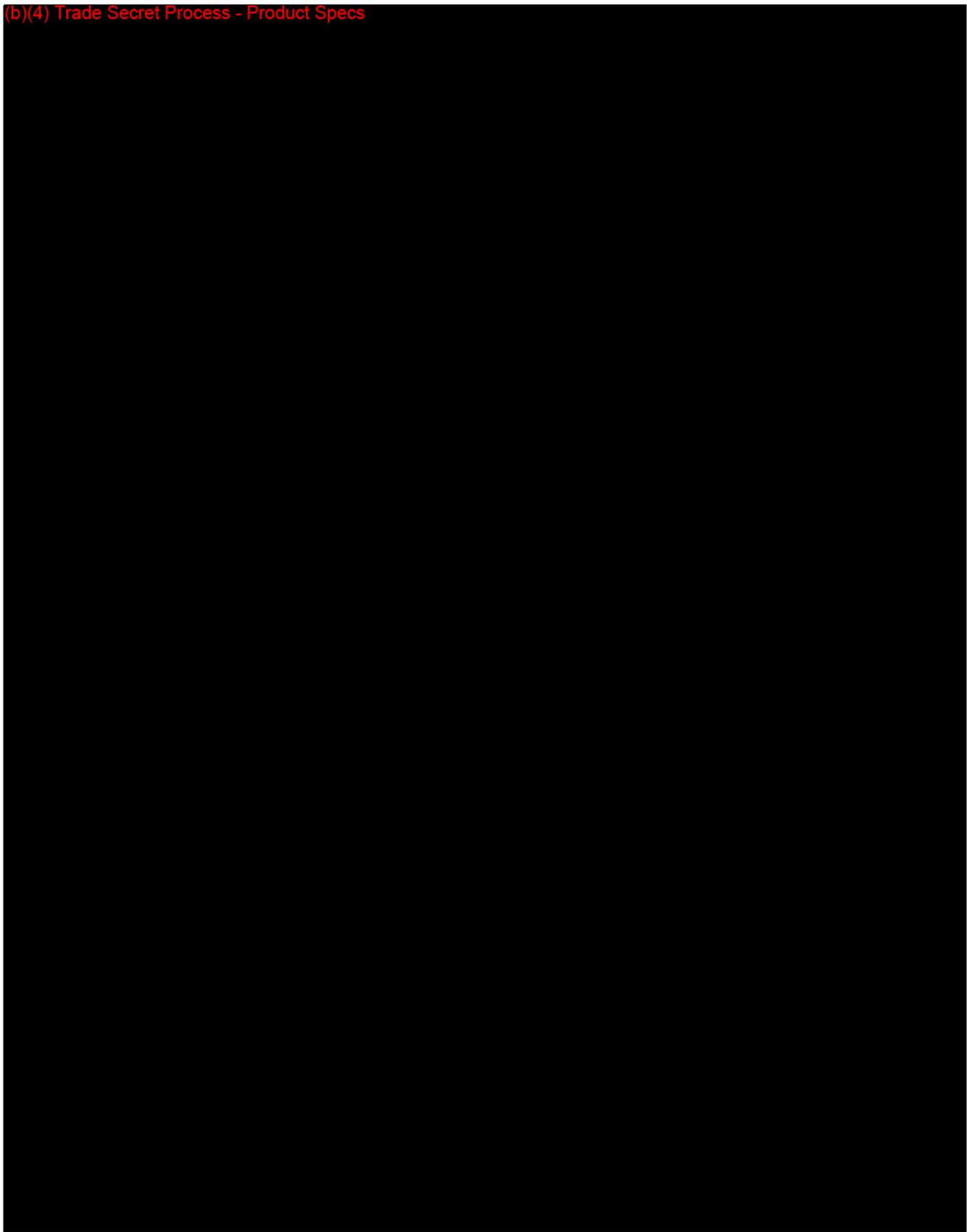
(b)(4) Trade Secret Process - Product Specs

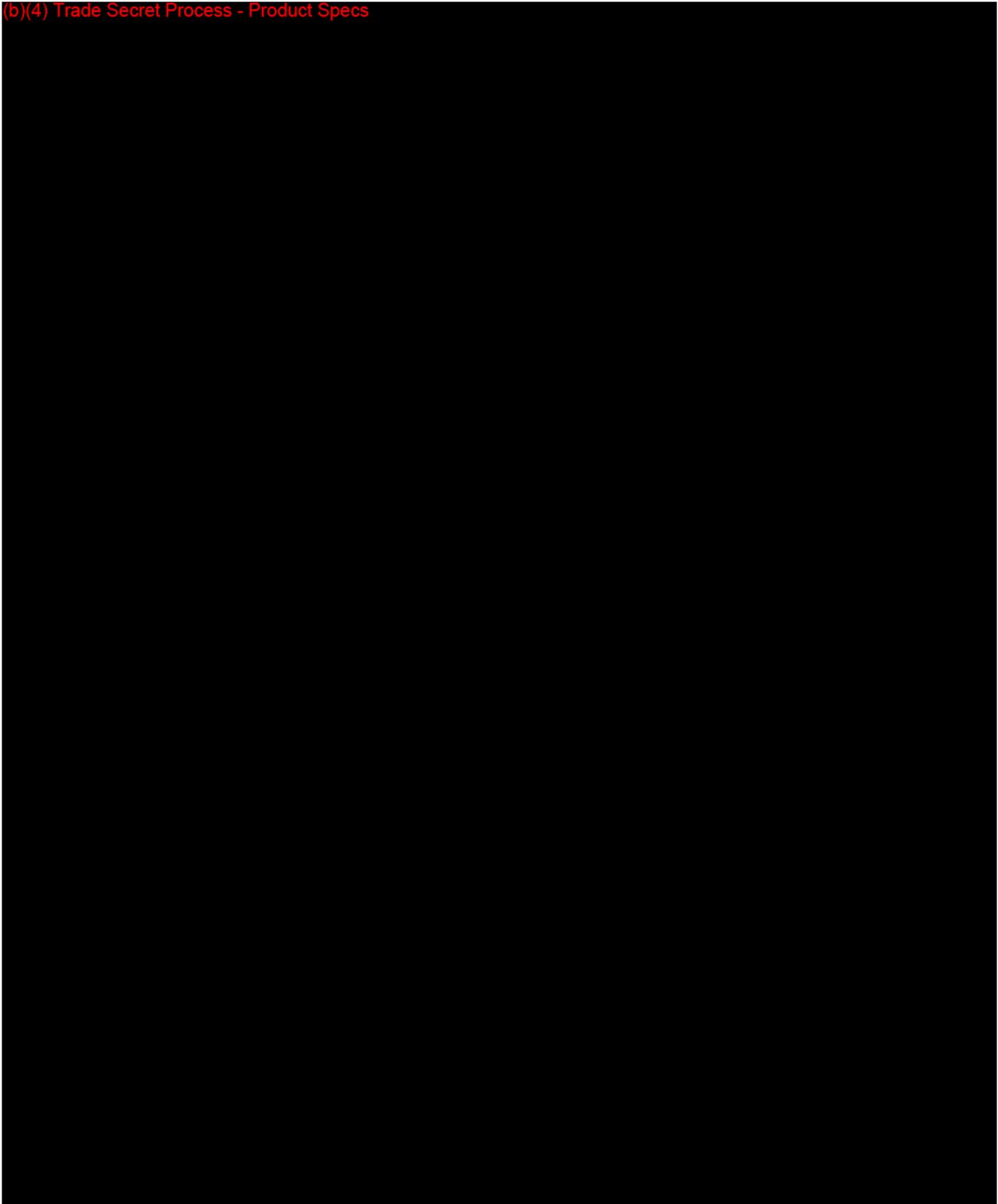


(b)(4) Trade Secret Process - Product Specs

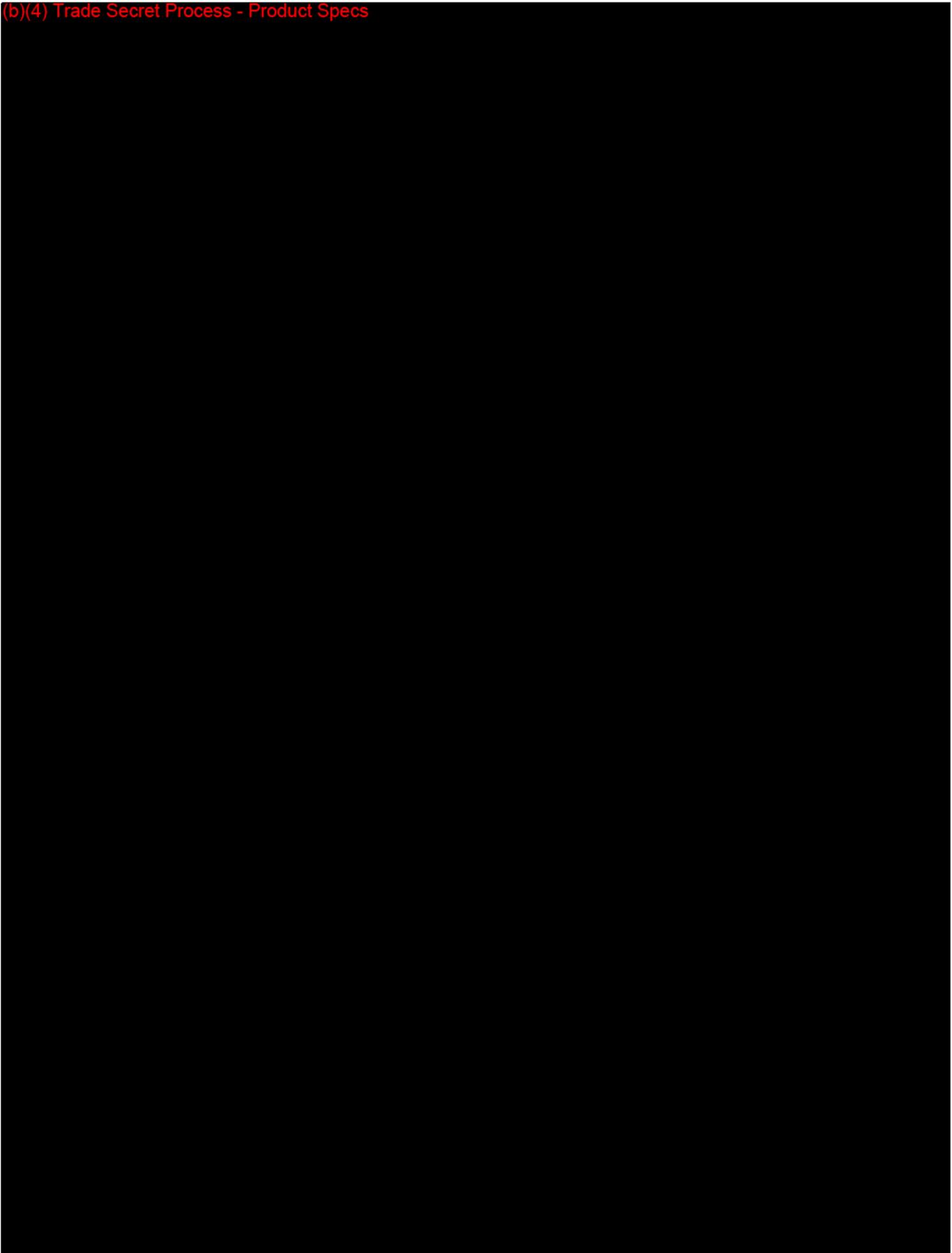


(b)(4) Trade Secret Process - Product Specs

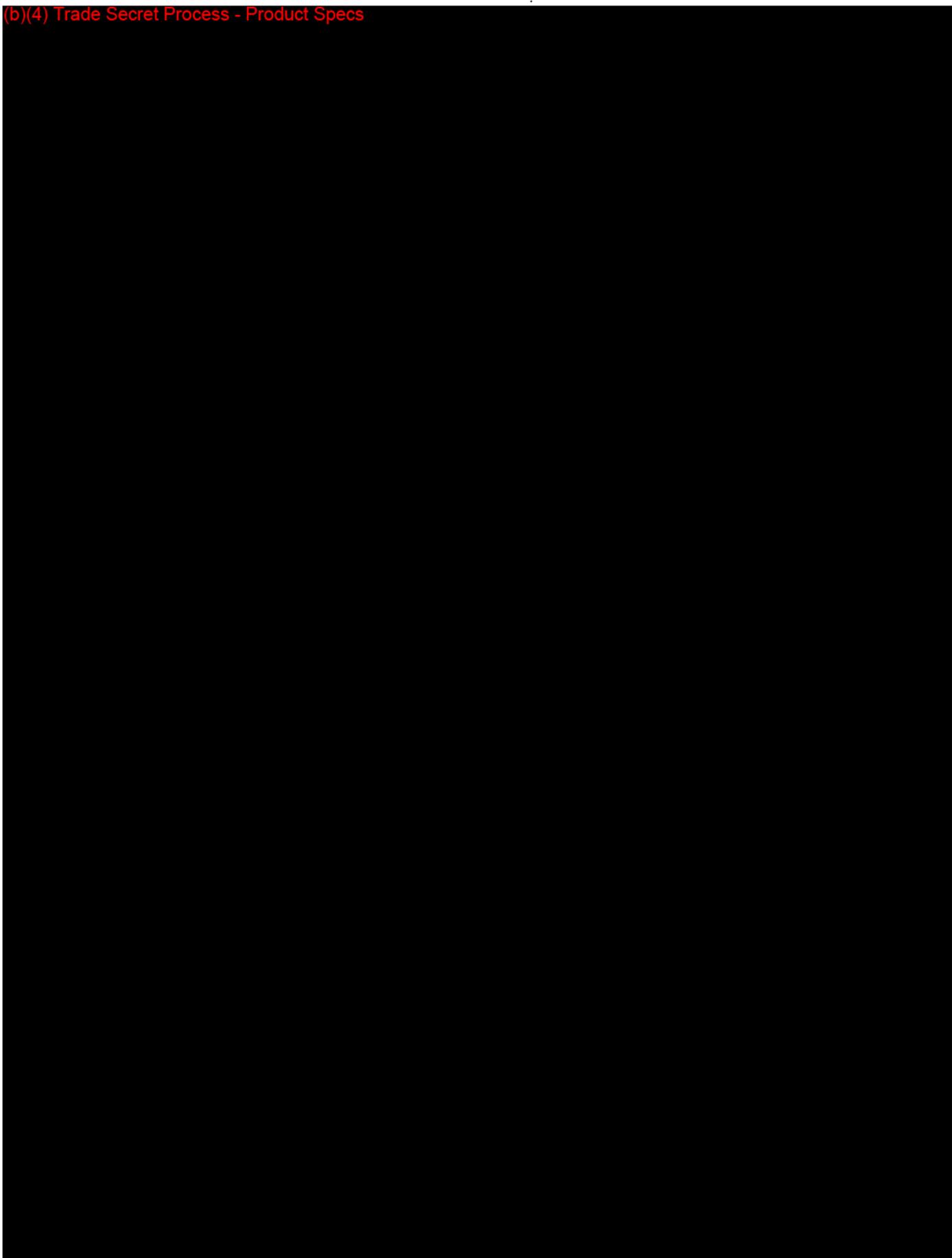




(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs





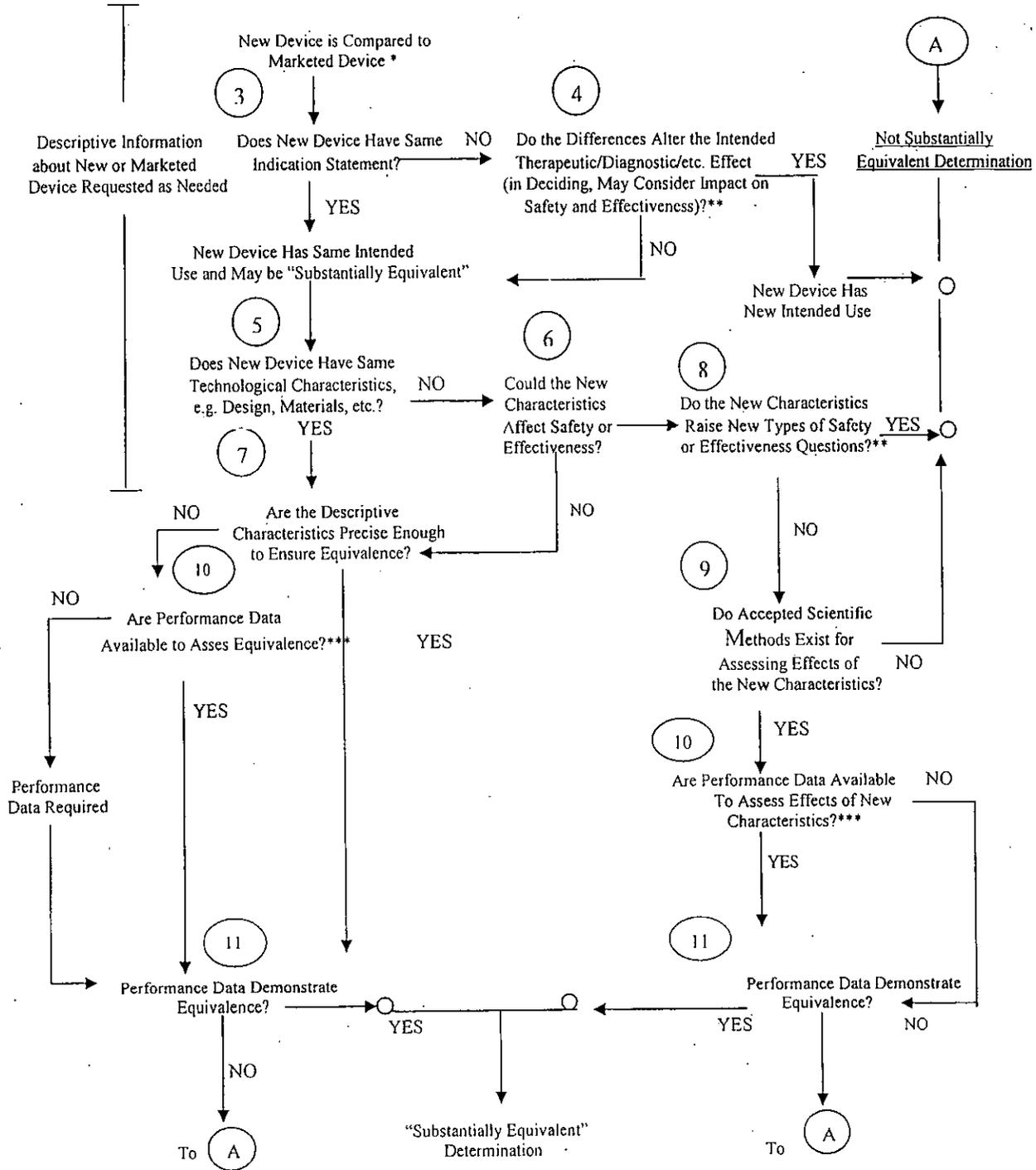
COVER SHEET MEMORANDUM

From: Reviewer Name Michel Janda
 Subject: 510(k) Number K093677/S
 To: The Record

Please list CTS decision code AI
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 Hold (Additional Information or Telephone Hold).
 Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Janda, Michel D

From: Janda, Michel D
Sent: Thursday, February 25, 2010 1:17 PM
To: 'Desai, Shibir'
Cc: Bandukwala, Abbas
Subject: Stryker Arthroscopy, K093677.

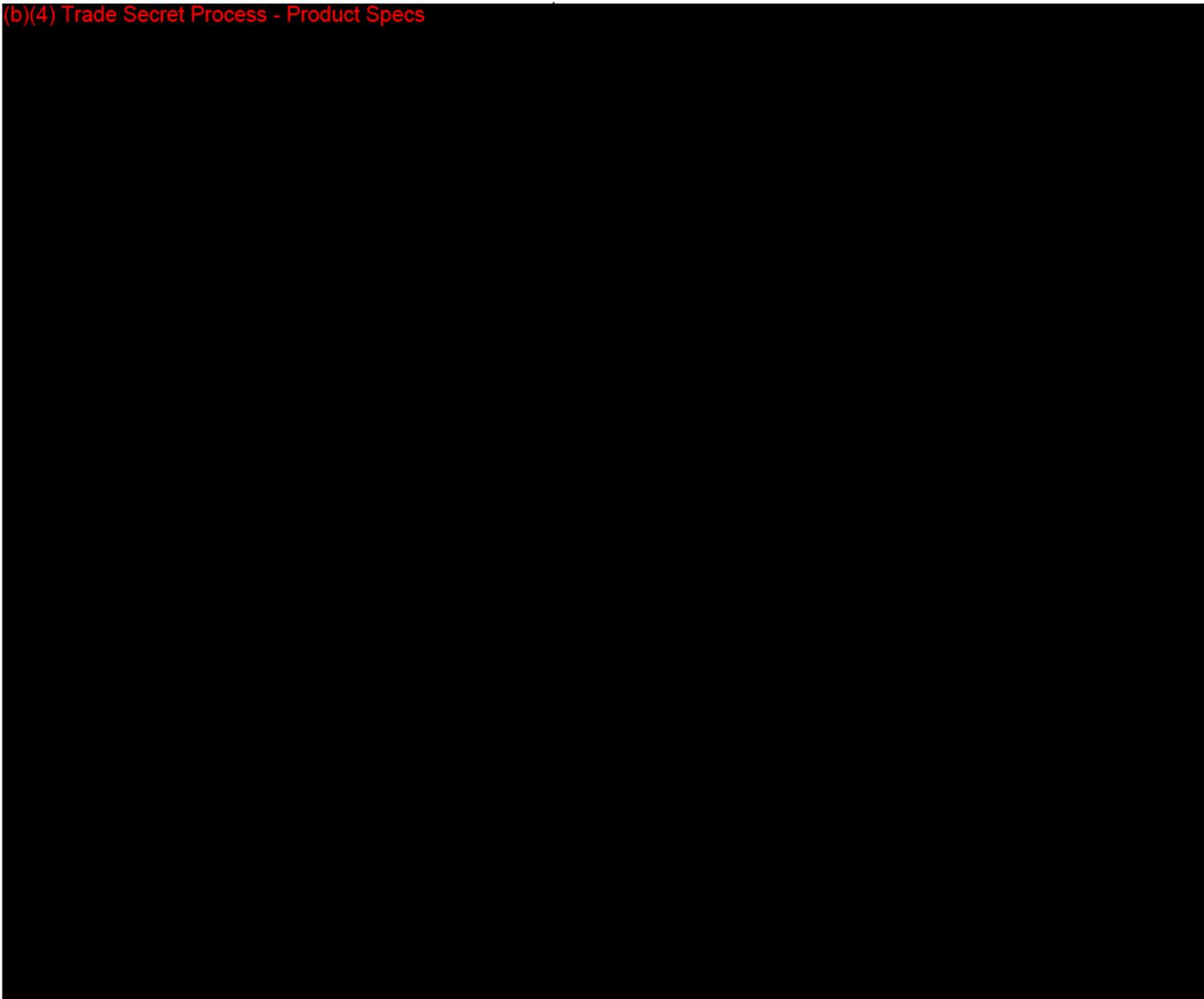
Shibir Desai
Regulatory Affairs Analyst

Stryker Endoscopy
5900 Optical Ct.
San Jose, CA 95138

Re: Stryker Arthroscopy, K093677.

Dear Shibir Desai,

(b)(4) Trade Secret Process - Product Specs



Sincerely,

Michel Janda
Biomedical Engineer
General Surgery Devices Branch
FDA/CDRH/ODE/DSORD
Phone #: (301) 796-6395
Fax #: (301) 847-8117

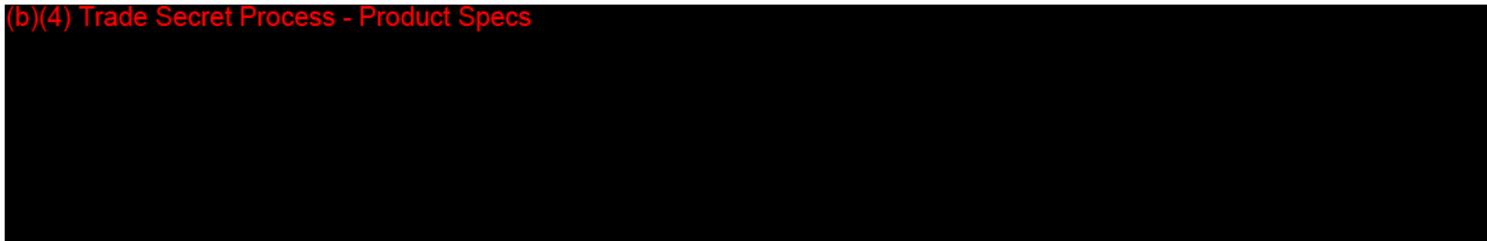
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

Janda, Michel D

From: Desai, Shibir [shibir.desai@stryker.com]
Sent: Thursday, February 18, 2010 12:36 PM
To: Janda, Michel D
Subject: RE: Stryker Arthroscope, K093677.
Attachments: FDA Request for Additional Information K093677.PDF

Dear Michel Janda,

(b)(4) Trade Secret Process - Product Specs



Best Regards,
Shibir Desai

From: Janda, Michel D [mailto:Michel.Janda@fda.hhs.gov]
Sent: Friday, February 12, 2010 10:20 AM
To: Desai, Shibir
Subject: RE: Stryker Arthroscope, K093677.

Dear Shibir Desai,

(b)(4) Trade Secret Process - Product Specs



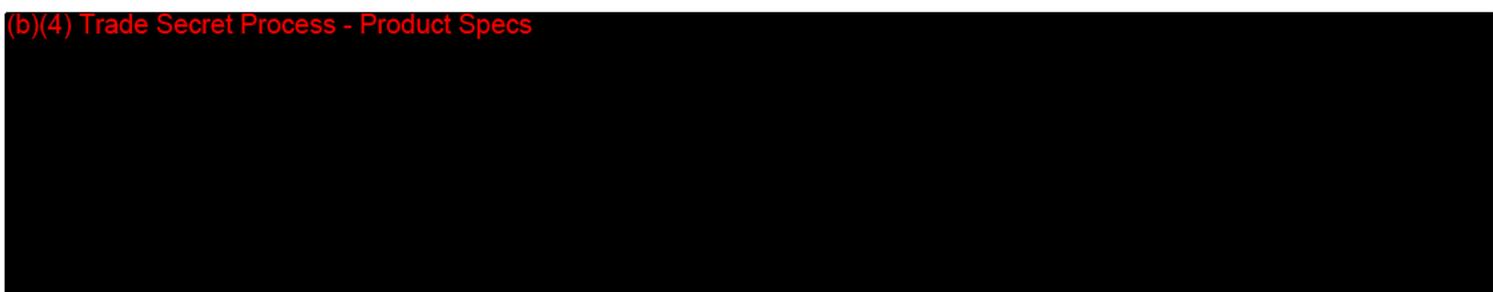
Sincerely,

Michel Janda

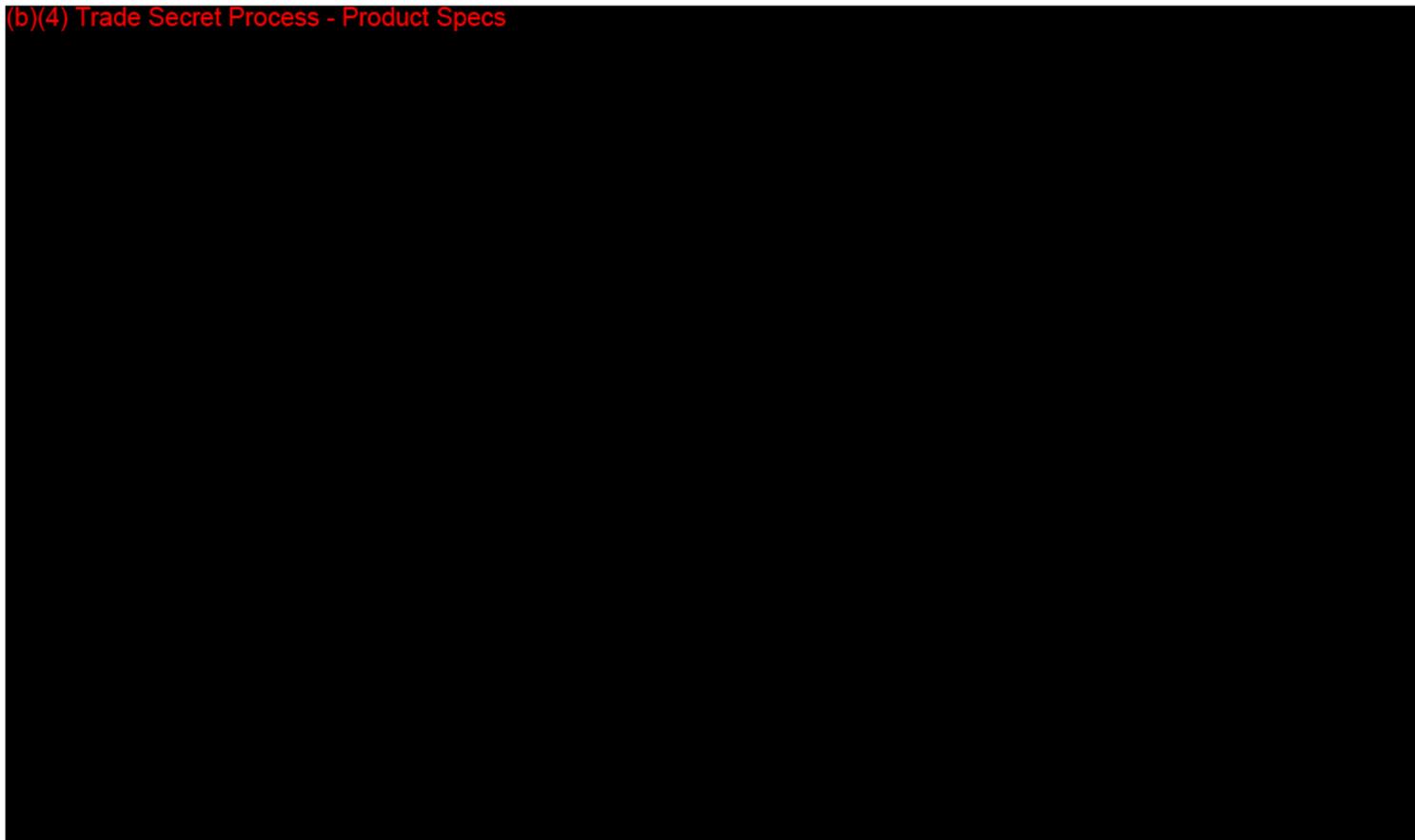
From: Desai, Shibir [mailto:shibir.desai@stryker.com]
Sent: Friday, February 05, 2010 3:36 PM
To: Janda, Michel D
Cc: Basu, Sankar
Subject: RE: Stryker Arthroscope, K093677.

Dear Michel Janda,

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



Best Regards,
Shibir Desai

From: Janda, Michel D [mailto:Michel.Janda@fda.hhs.gov]
Sent: Friday, February 05, 2010 6:54 AM
To: Desai, Shibir
Cc: Basu, Sankar
Subject: Stryker Arthroscope, K093677.

Shibir Desai

Regulatory Affairs Analyst

Stryker Endoscopy

5900 Optical Ct.

San Jose, CA 95138

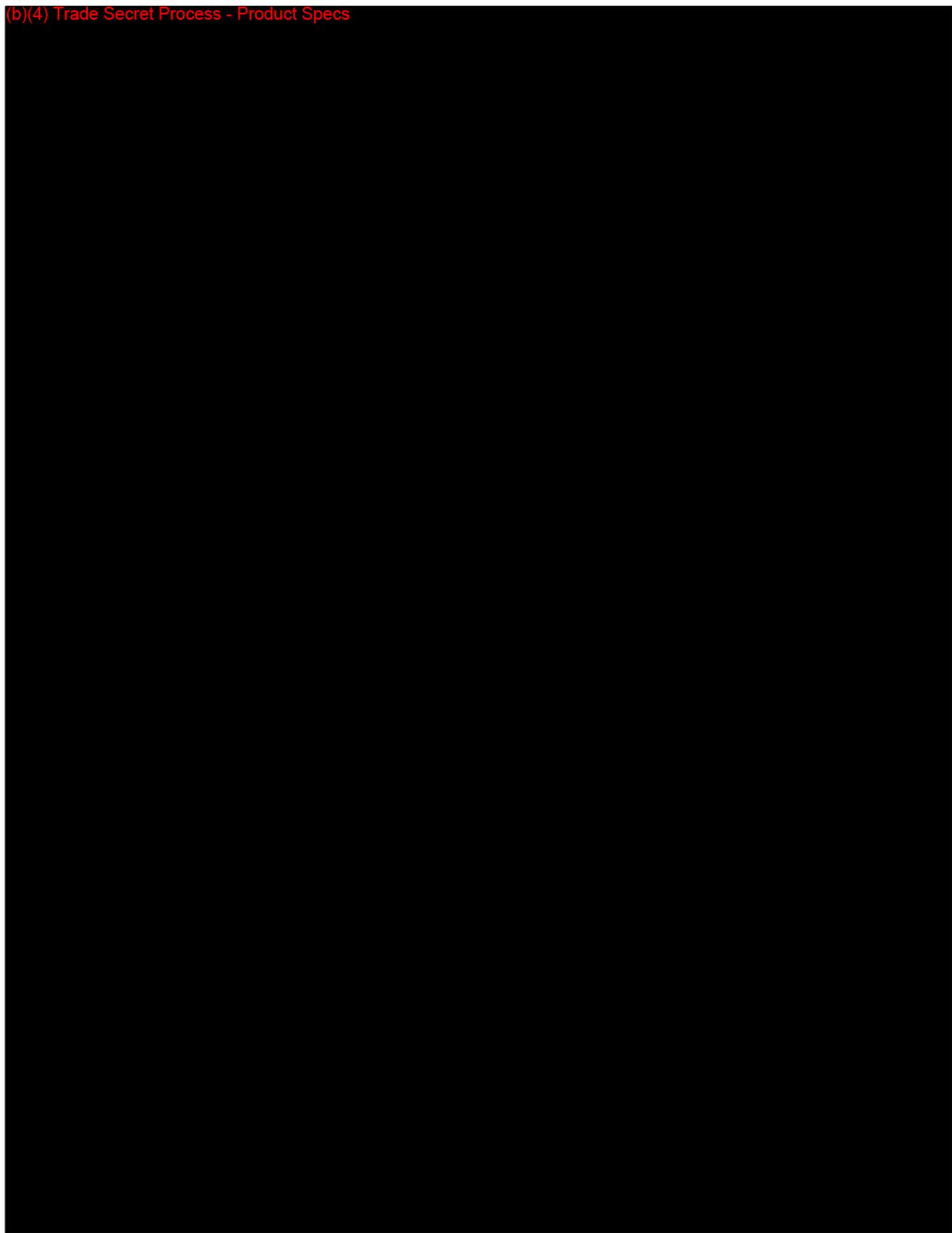
Re: Stryker Arthroscope, K093677.

Dear Shibir Desai,

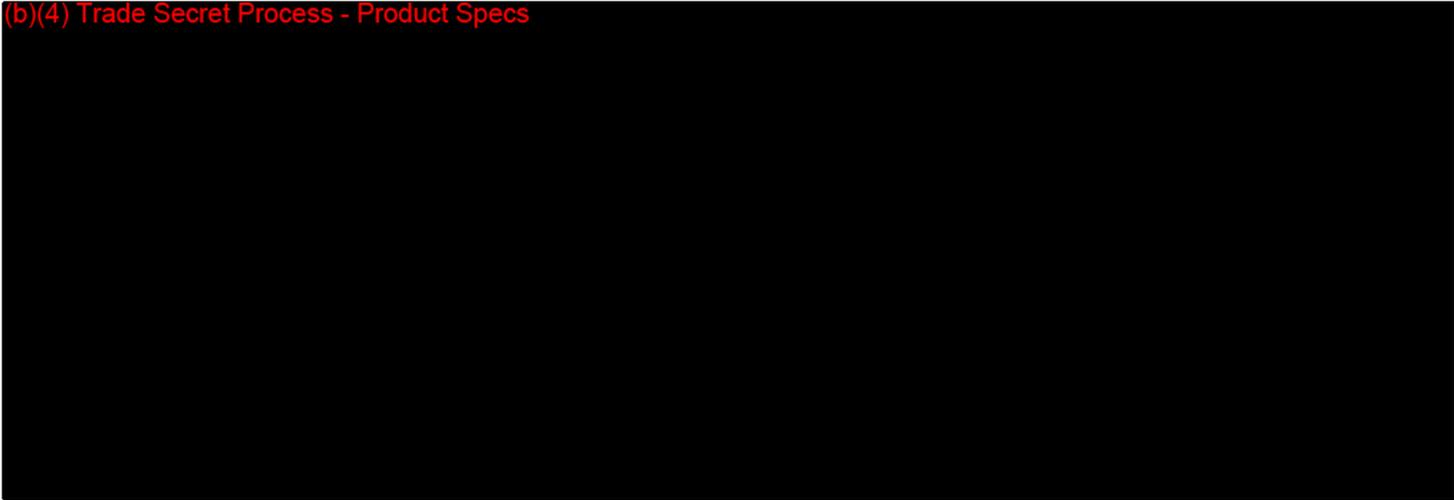
(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



Sincerely,

Michel Janda

Biomedical Engineer

General Surgery Devices Branch

FDA/CDRH/ODE/DSORD

Phone #: (301) 796-6395

Fax #: (301) 847-8117

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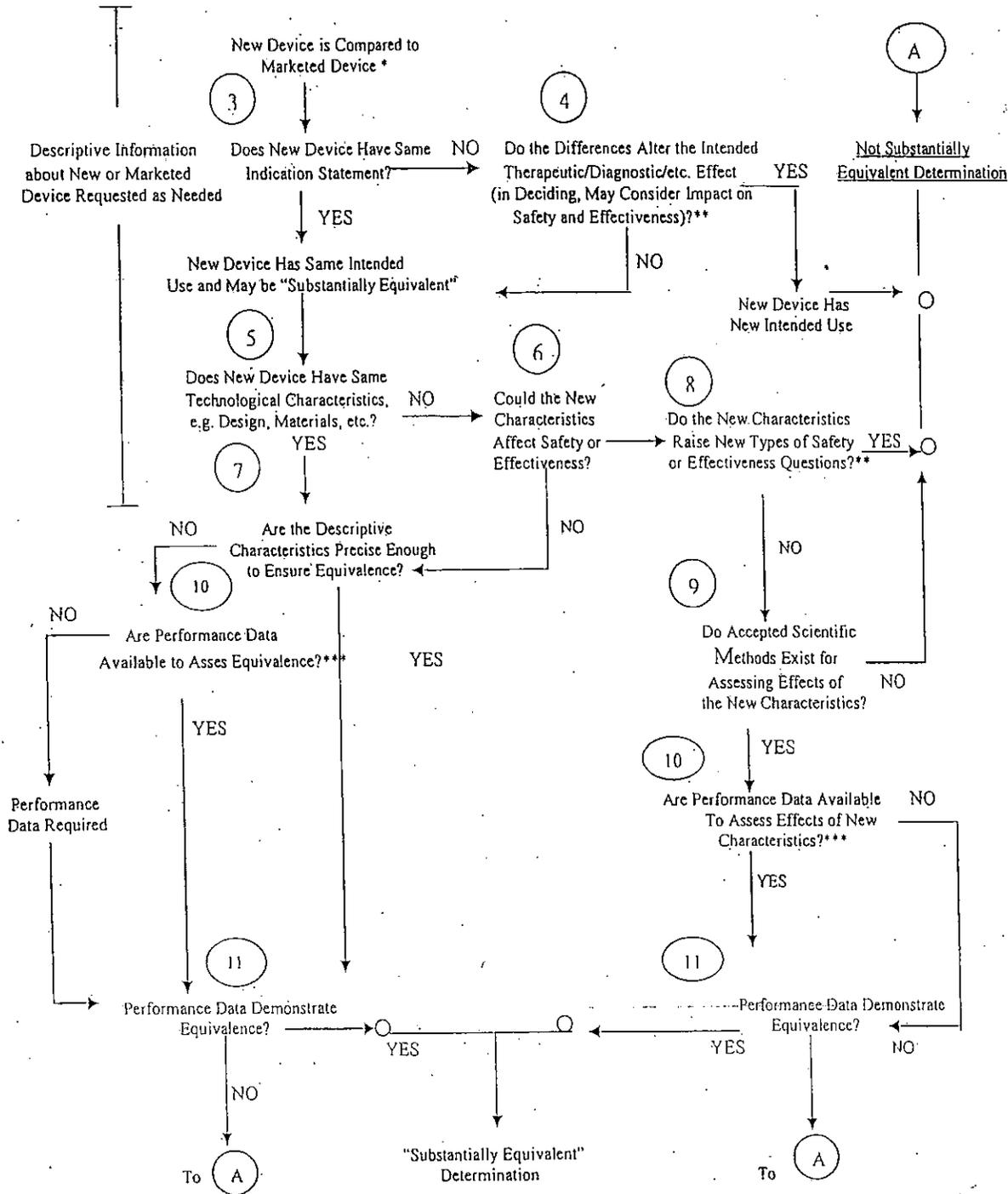
COVER SHEET MEMORANDUM

From: Reviewer Name Michel Janda
 Subject: 510(k) Number K093677
 To: The Record

- Please list CTS decision code AI
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information ~~or Telephone Hold~~)
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Janda, Michel D

From: Janda, Michel D
Sent: Friday, February 05, 2010 9:54 AM
To: 'Shibir.Desai@Stryker.com'
Cc: Basu, Sankar
Subject: Stryker Arthroscope, K093677.

Shibir Desai
Regulatory Affairs Analyst

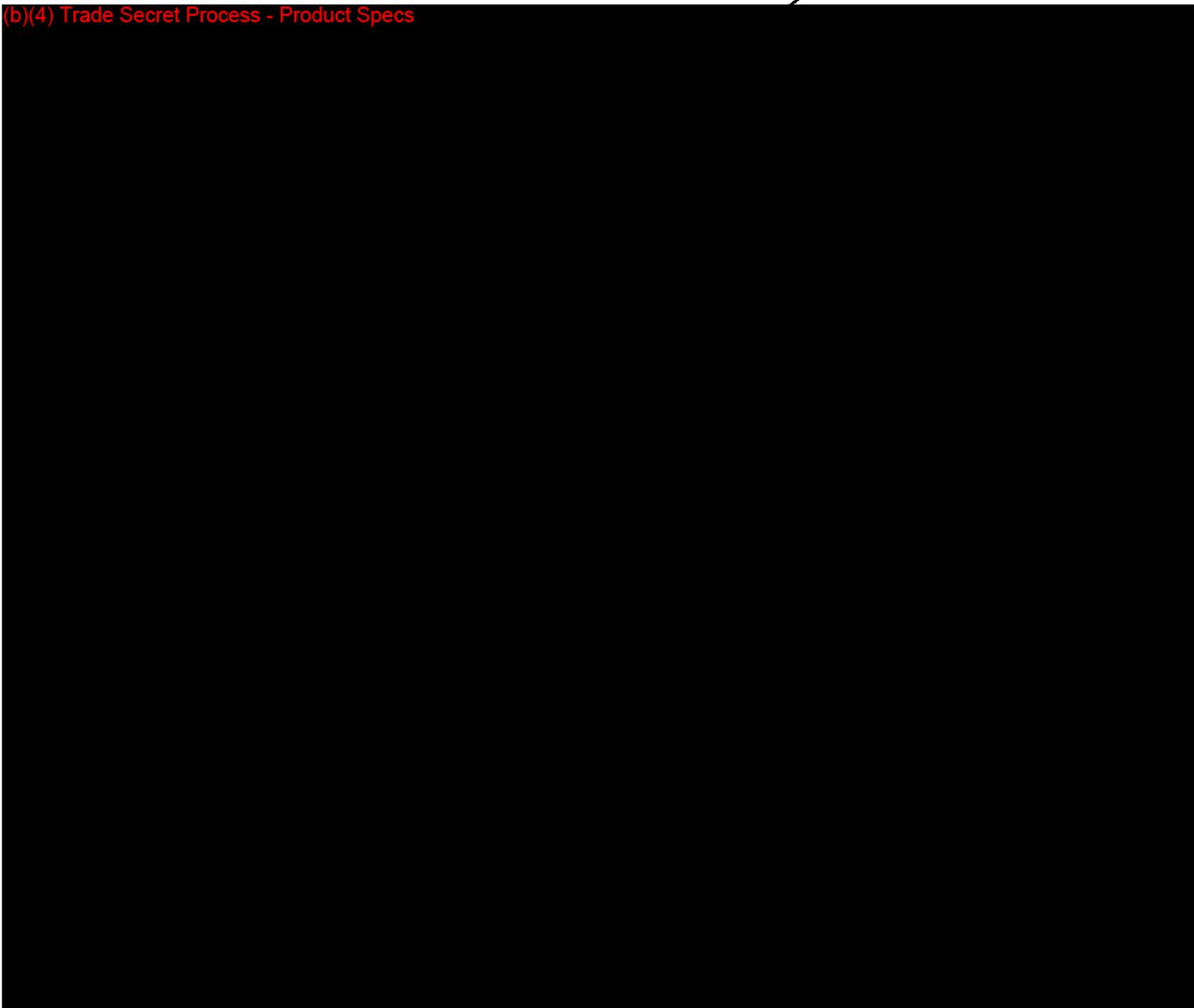
Stryker Endoscopy
5900 Optical Ct.
San Jose, CA 95138

Re: Stryker Arthroscope, K093677.

Dear Shibir Desai,

*Agree PAK
2/5/10*

(b)(4) Trade Secret Process - Product Specs

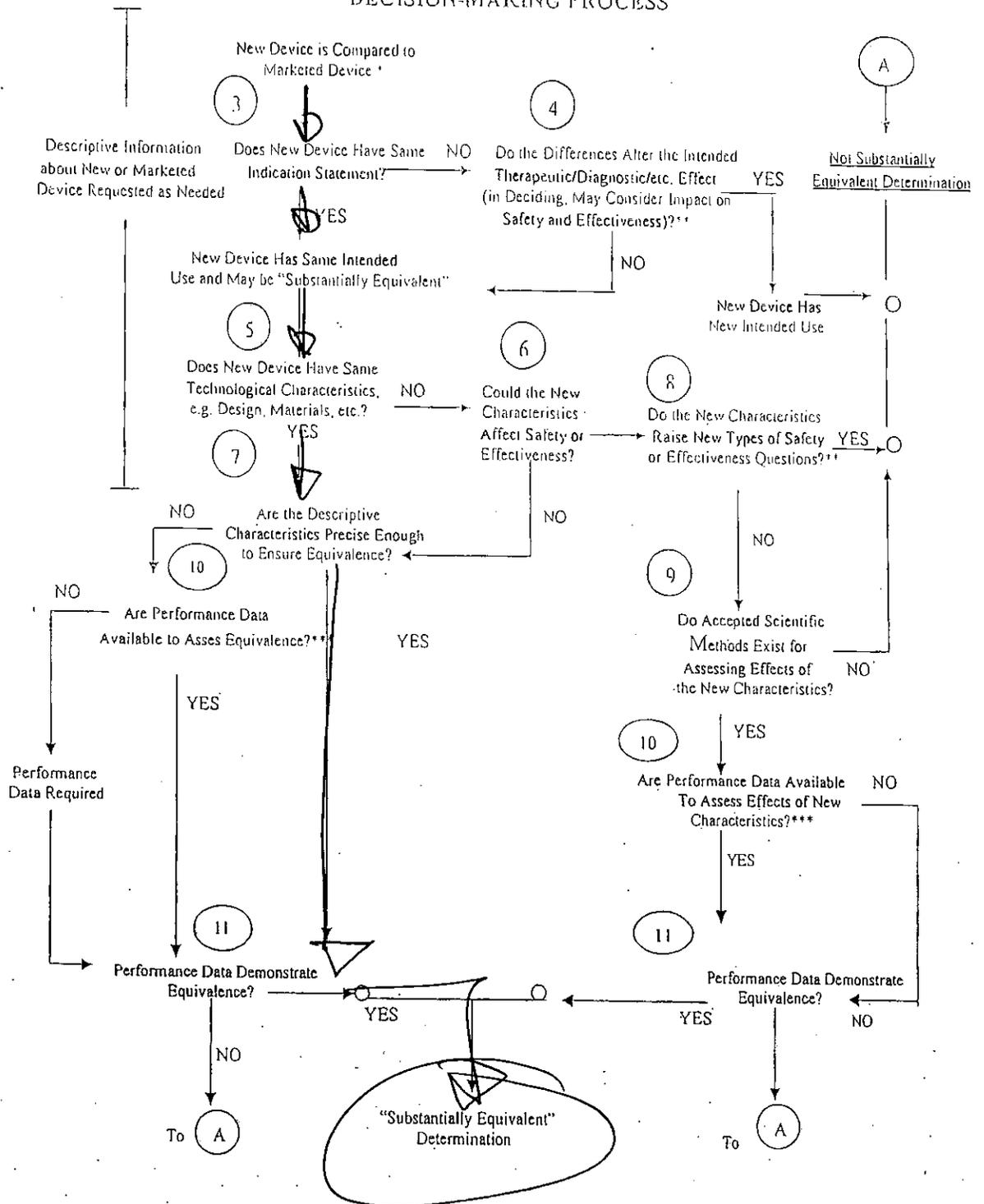


Sincerely,

Michel Janda
Biomedical Engineer
General Surgery Devices Branch
FDA/CDRH/ODE/DSORD
Phone #: (301) 796-6395
Fax #: (301) 847-8117

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 22, 2010

STRYKER ENDOSCOPY
ENDOSCOPY DIVISION
5900 OPTICAL CT.
SAN JOSE, CALIFORNIA 95138
UNITED STATES
ATTN: SHIBIR DESAI

510k Number: K093677

Product: STRYKER ARTHROSCOPE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

5900 Optical Ct
San Jose, CA 95138
t: 408 754 2784 f: 408 754 2914

K093677/S **stryker**[®]
Endoscopy

FDA CDRH DMC

February 16, 2010

FEB 19 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

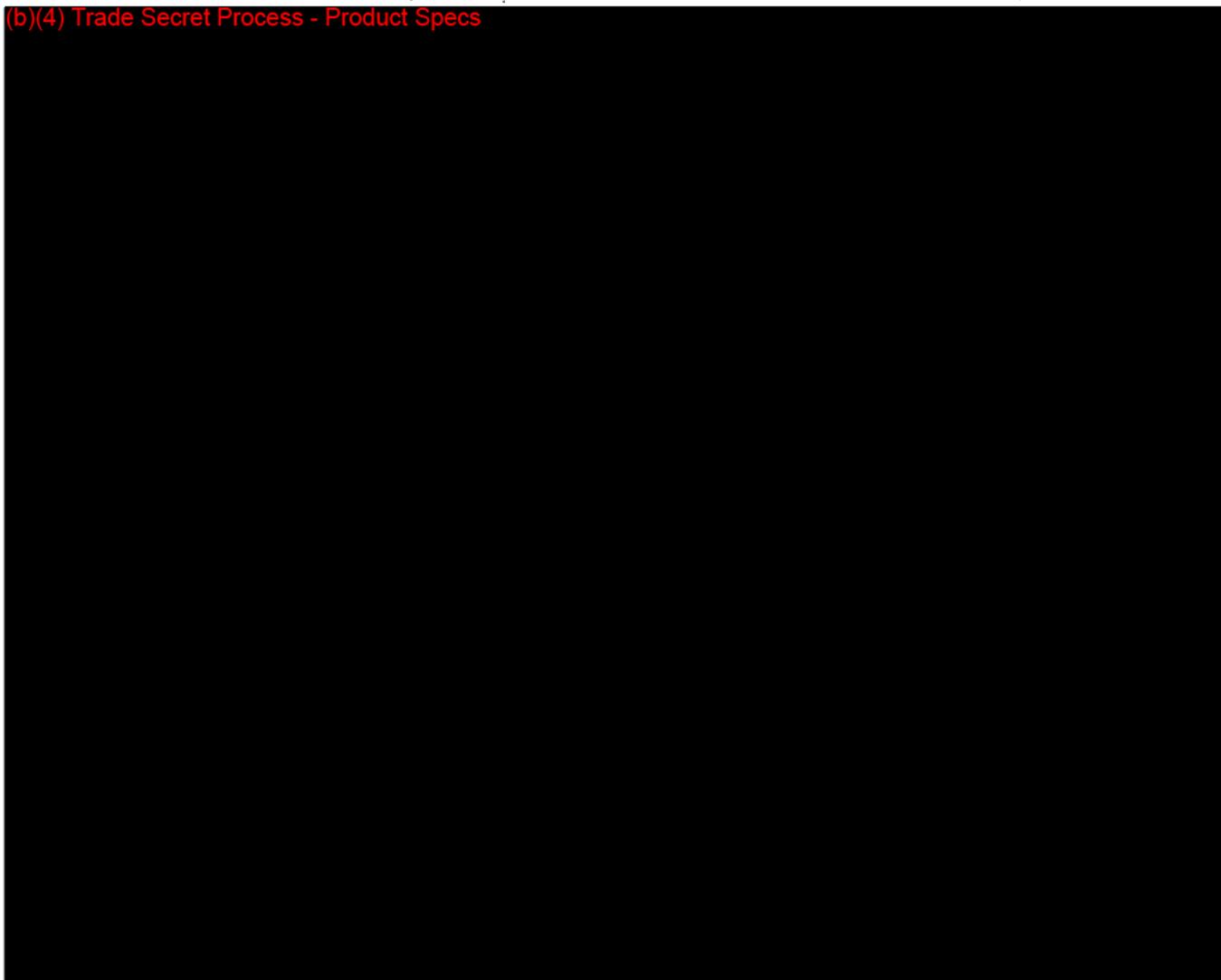
Received

Attention: Michel Janda

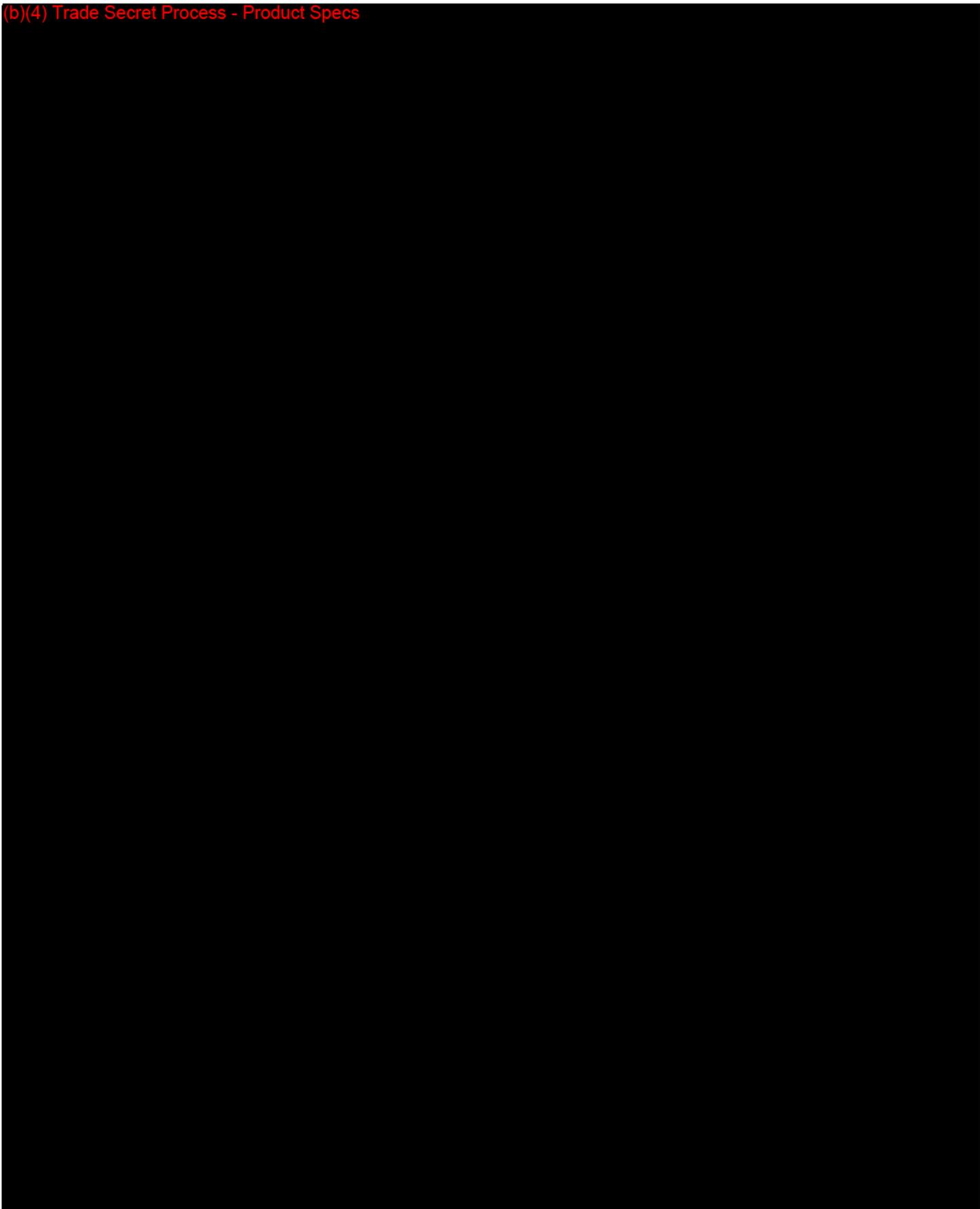
Re: Stryker Arthroscope, K093677.

Dear Mr. Michel Janda,

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

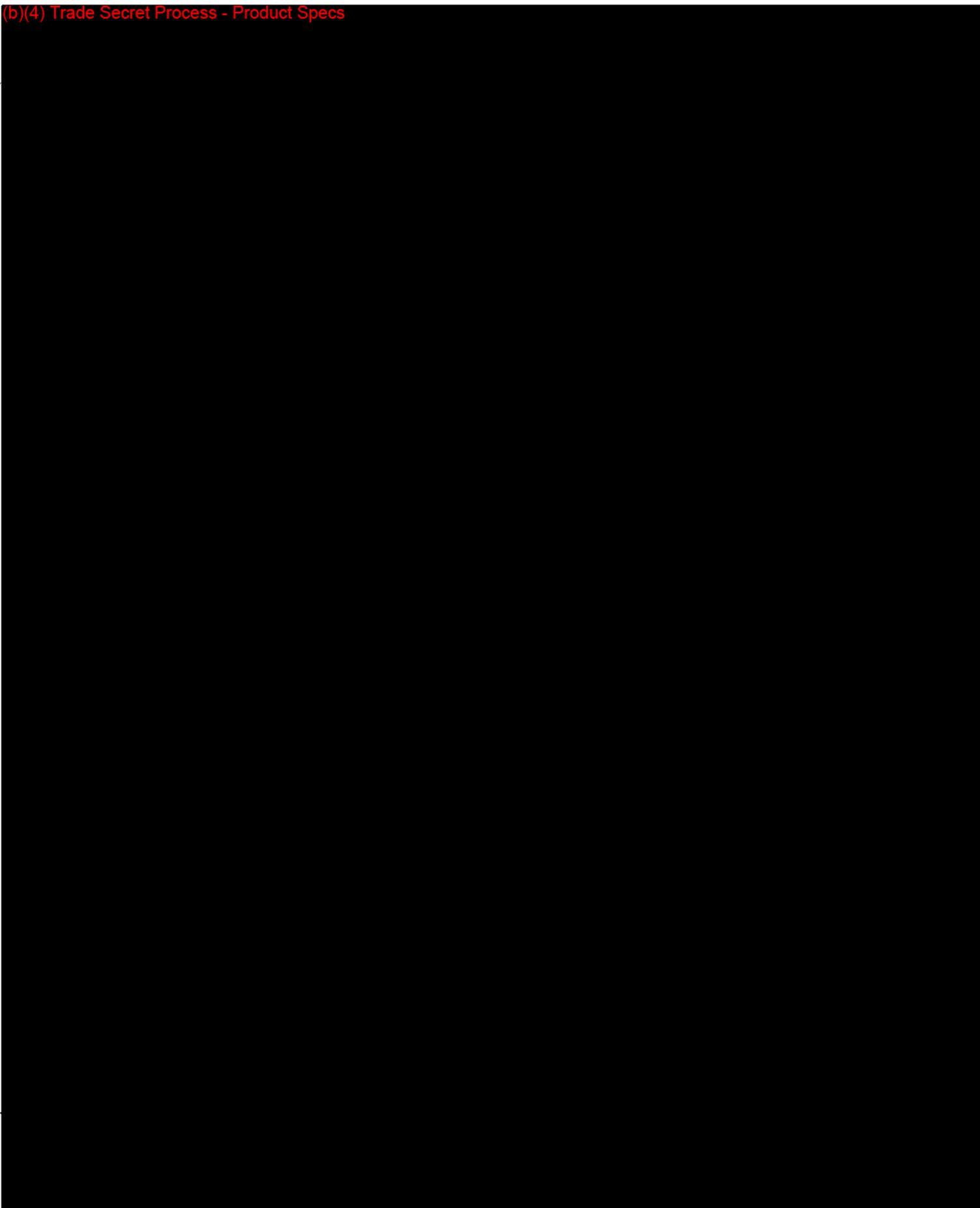


Technological Characteristics: The Stryker Arthroscopes are substantially equivalent in construction and materials to the predicate Henke Sass Wolf Arthroscopes (K080560).

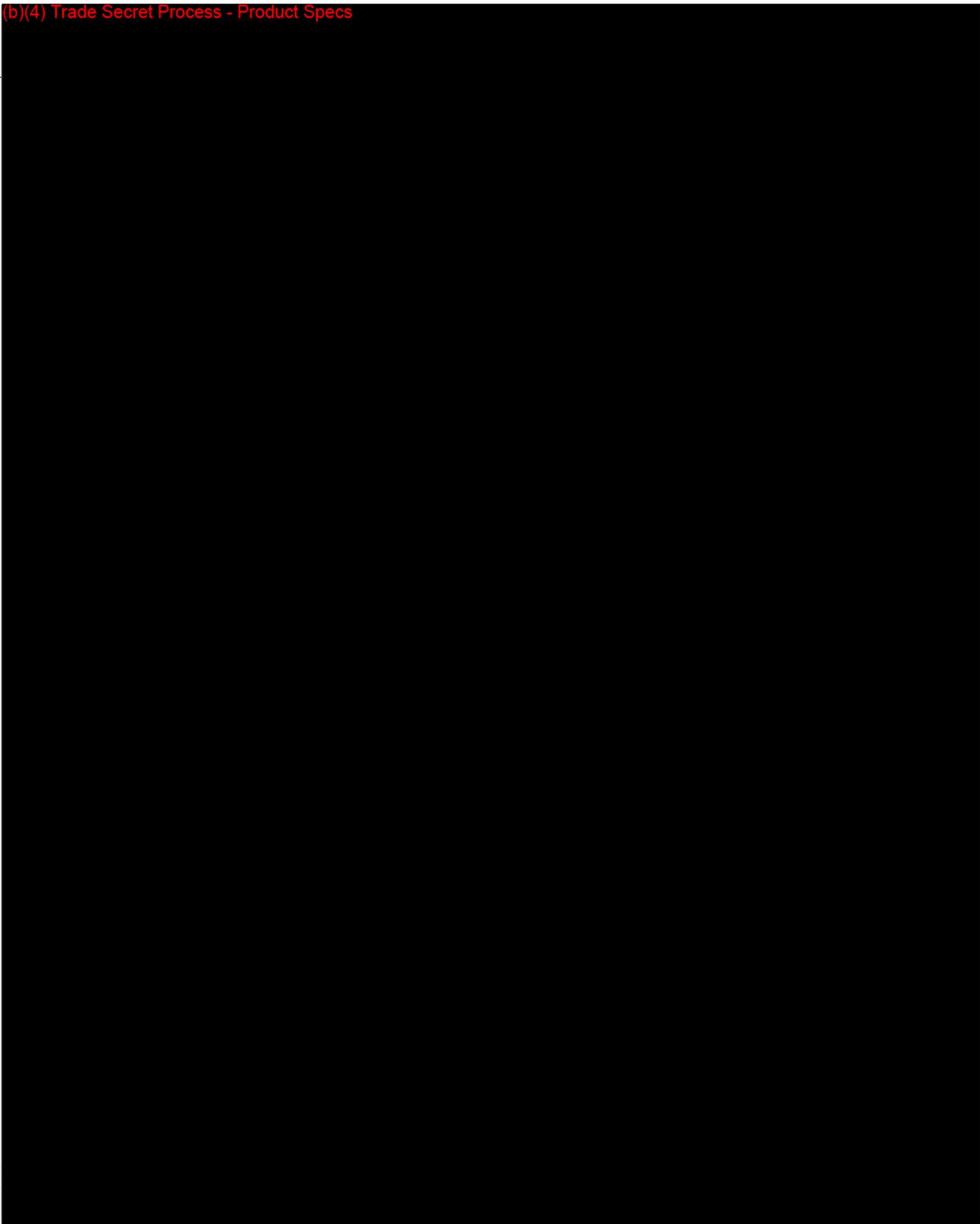
	Proposed Device	Predicate Device	Equivalence	Impact on Safety and Effectiveness
Device	Stryker Arthroscope	HSW Arthroscope		
Technological Characteristics (Design)				
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°	Different	The differences in the Field of view do not affect the safety and efficacy of the device.
Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°	Same	N/A
Outer Diameter	4mm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm	Same	N/A
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm	Different	The lengths are within the range of the predicate. The differences in the length do not affect the safety and efficacy of the device.
Single Use or Reusable	Reusable	Reusable	Same	Equivalent
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics	Same	N/A

(b)(4) Trade Secret Process - Product Specs

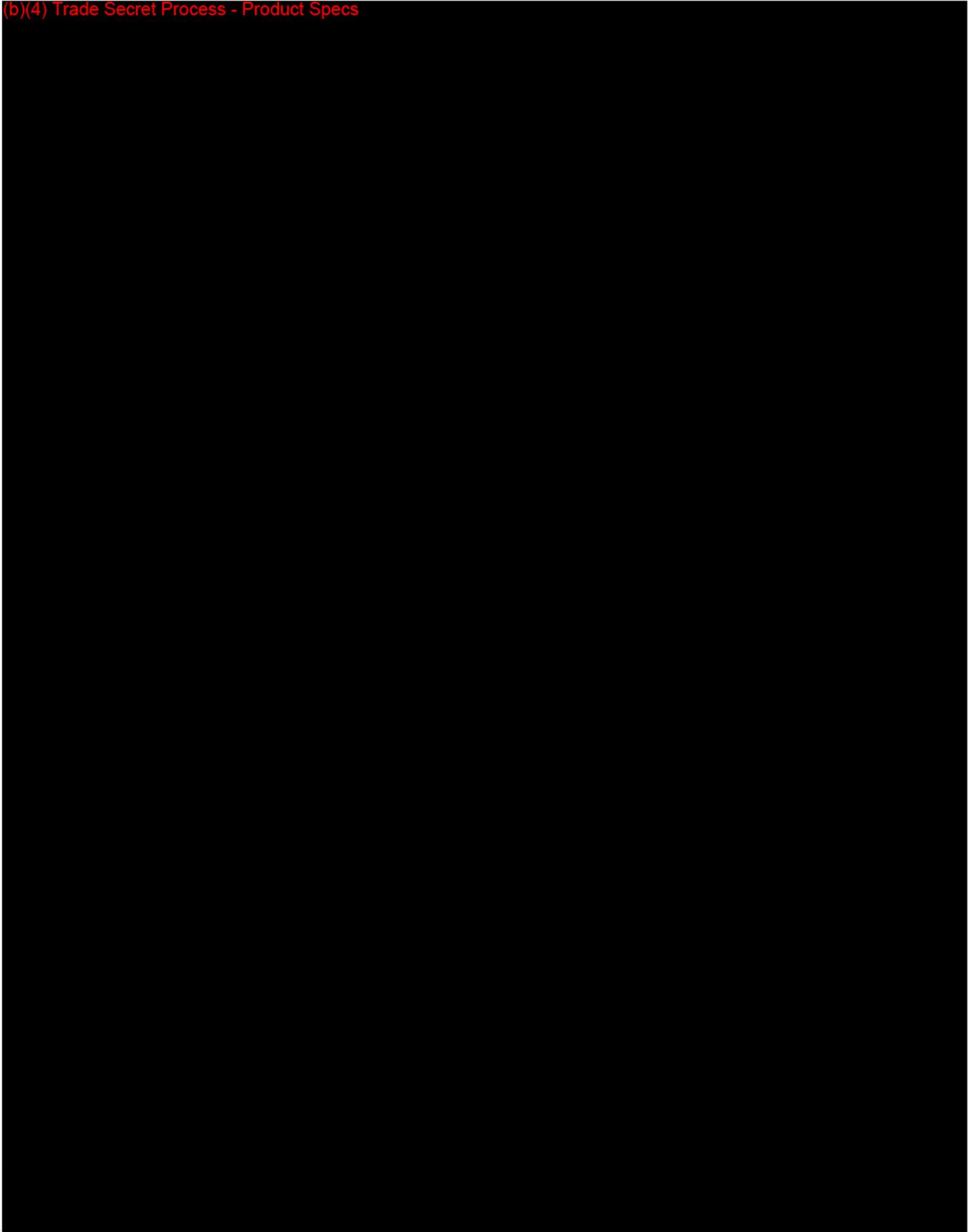
(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

If you should have any further questions regarding this response, please feel free to contact me via email at Shibir.Desai@stryker.com or via phone at 408-754-2540.

Sincerely,



Shibir Desai

Regulatory Affairs Analyst
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95136
t: (408) 754-2540
Shibir.Desai@stryker.com

ATTACHMENT 1

TAB 1

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-1	International Organization for Standardization	Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing	3ED 2003	08/01/2003
2	ISO 10993-10	International Organization for Standardization	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity	3ED 2003	08/01/2003
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of the Chief Information Officer (HFA-710)
 5600 Fishers Lane
 Rockville, Maryland 20857

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90

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-98

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (G95-1)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Testing	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Options 5.2.2, 5.2.3, 5.2.5, and 5.2.6 were selected.

DESCRIPTION

5.2.2 - Cytotoxicity; 5.2.3 - Sensitization; 5.2.5 - Intracutaneous Reactivity; 5.2.6 - Systemic Toxicity (acute toxicity)

JUSTIFICATION

External communicating device contacting tissue/bone/dentin for <24 hours

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of biological evaluation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Assurance of test methods	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-87

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (G95-1)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Pretest Considerations	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

6.1 Not applicable; Option 6.3 selected over 6.4

DESCRIPTION

6.1 - In vitro irritation tests; 6.3 - Animal Skin Irritation Test; 6.4 - Human Skin Irritation Test

JUSTIFICATION

6.1 Not recommended per standard; 6.3 Irritation testing in animals helps identify materials which may be potential human irritants

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed Hypersensitivity Tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Option 7.4 selected over 7.5

DESCRIPTION

7.4 - Maximization test for delayed hypersensitivity; 7.5 - Closed-patch test for delayed hypersensitivity

JUSTIFICATION

7.4 Most sensitive method, preferred for single chemicals, and reported to be useful for evaluation of extracts

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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Rockville, MD 20850

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TAB 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Proprietary Name: Stryker Arthroscope
 Common and Usual Names: Stryker Arthroscope
 Classification Name: Arthroscope (21 CFR § 888.1100, Product Code HRX)

Intended Use: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

Device Description: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. The Stryker Arthroscope is a long tube containing a series of lenses. At the distal end, an objective lens captures the image of the object. Lens along the rod relay the image. At the proximal end, a proximal coupling lens relays the image to a CCD (Camera).

The Stryker Arthroscopes come in various diameters including 1.9mm, 2.3mm, 2.7mm, and 4.0mm, although other sizes are sometimes offered. Larger size arthroscopes are used for general viewing, while smaller diameter arthroscopes are used for restricted surgical sites. The Stryker Arthroscopes come in several directions of view including, 0°, 30°, 45°, 70°, although other direction of views are sometimes offered. The direction of view enables viewing of different parts. Materials of the Arthroscope include stainless steel, titanium, PEEK, Glass, and Sapphire.

Technological Characteristics: The Stryker Arthroscopes are substantially equivalent in construction and materials to the predicate Henke Sass Wolf Arthroscopes (K080560).

	Proposed Device	Predicate Device	Equivalence	Impact on Safety and Effectiveness
Device	Stryker Arthroscope	HSW Arthroscope		
Technological Characteristics (Design)				
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°	Different	The differences in the Field of view do not affect the safety and efficacy of the device.
Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°	Same	N/A

Outer Diameter	4mm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm	Same	N/A
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm	Different	The lengths are within the range of the predicate. The differences in the length do not affect the safety and efficacy of the device.
Single Use or Reusable	Reusable	Reusable	Same	Equivalent
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics	Same	N/A

Voluntary Safety and Performance Standards: The Stryker Arthroscopes conform to the voluntary standards including but not limited to (Refer to **Section 5.1**):

Biological Evaluation of Medical Devices

10993-1: Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing

10993-10: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

Electrical Safety Requirements Per 60601

IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-2-18: Medical Electrical Equipment - Part 2: Particular Requirements for the safety of endoscopic equipment

AAMI/ISO Standards for Sterilization of Medical Devices

TIR 12: Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities

ISO 14937: Sterilization of Health Care Products - General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices

Optics

ISO 8600-1: Optics and photonics — Medical endoscopes and endotherapy devices — Part 1: General requirements

ISO 8600-3: Optics and optical instruments: Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics

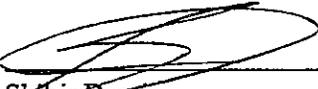
ISO 8600-5: Optics and photonics-Medical Endoscopes and Endoscopic Accessories-Part 5: Determination of Optical Resolution of rigid endoscopes with optics.

Performance Testing: The subject device has been subjected to and passed electrical safety, sterilization, and biocompatibility testing requirements. The patient contacting materials are identical to the materials used in the predicated device (Henke Sass Wolf Arthroscope K080560). The Stryker Arthroscopes met all specified design and performance requirements.

Predicate Devices: The Stryker Arthroscopes are substantially equivalent in terms of safety and effectiveness to the currently marketed device, Henke Sass Wolf Arthroscopes (K080560).

Substantial Equivalence: The technological differences between the Stryker Arthroscope and Henke Sass Wolf Arthroscopes do not raise new questions of safety or effectiveness. Therefore the Stryker Arthroscopes are substantially equivalent to the previously cleared Henke Sass Wolf Arthroscope (K080560). Refer to Section 7.0 for a detailed comparison.

Contact:



Shibir Desai
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5900 Optical Court
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Fax: 408-754-2521
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Feb 17, 2010

Date:



TAB 3

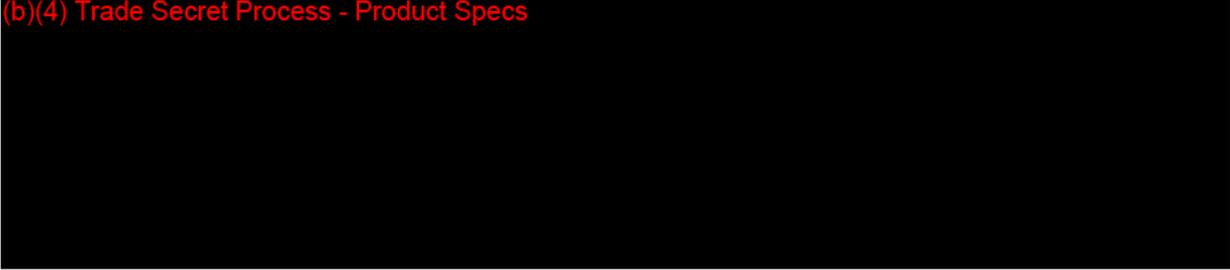
3.0 **DEVICE IDENTIFICATION**

3.1 **Proposed Device Name**

Table 2

Proprietary Name:	Stryker Arthroscope
Common and Usual Name:	Stryker Arthroscope

(b)(4) Trade Secret Process - Product Specs



4.0 **CLASSIFICATION AND PRODUCT CODE**

Table 4

Classification Name	Product Code	Product Class	Regulation Number
Arthroscope	HRX	II	888.1100

5.0 **SECTION 514 SPECIAL CONTROLS**

No performance standards or special controls have been established under section 514 of the Federal Food, Drug, and Cosmetic Act.

However, Stryker Endoscopy has chosen to comply with the following voluntary standards:

5.1. Voluntary Standards

The Stryker Arthroscopes conform to the voluntary standards including but not limited to:

Biological Evaluation of Medical Devices

10993-1: Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing

10993-10: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

Electrical Safety Requirements Per 60601

IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-2-18: Medical Electrical Equipment - Part 2: Particular Requirements for the safety of endoscopic equipment

AAMI/ISO Standards for Sterilization of Medical Devices

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Optics

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ISO 8600-5: Optics and photonics-Medical Endoscopes and Endoscopic Accessories-Part 5: Determination of Optical Resolution of rigid endoscopes with optics.

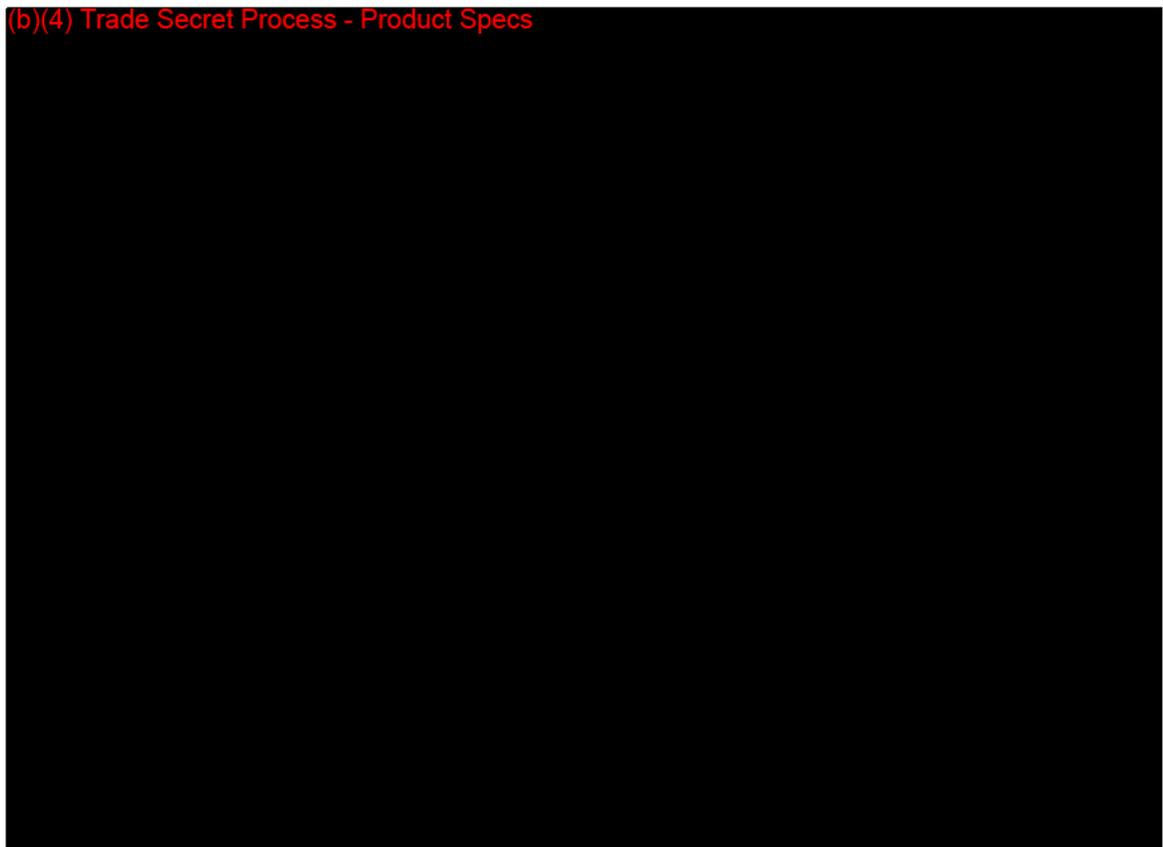
6.0 DEVICE DESCRIPTION

6.1. Intended Use

Stryker **Arthroscopes** are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

6.2. System Description and Video System Diagram

(b)(4) Trade Secret Process - Product Specs



TAB 4

TAB 5

TAB 6

TAB 7

Appendix A: Sterilization Validation for Instruments

Appendix B: Adoption for Instruments

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Appendix C: Common Sterilization Cycles

TAB 8

TAB 9

TAB 10



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 02, 2010

STRYKER ENDOSCOPY
ENDOSCOPY DIVISION
5900 OPTICAL CT.
SAN JOSE, CALIFORNIA 95138
UNITED STATES
ATTN: SHIBIR DESAI

510k Number: K093677

Product: STRYKER ARTHROSCOPE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

5900 Optical Ct
San Jose, CA 95138
t: 408 754 2784 f: 408 754 2914

K093677/S2

February 26, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

MAR - 2 2010

Received

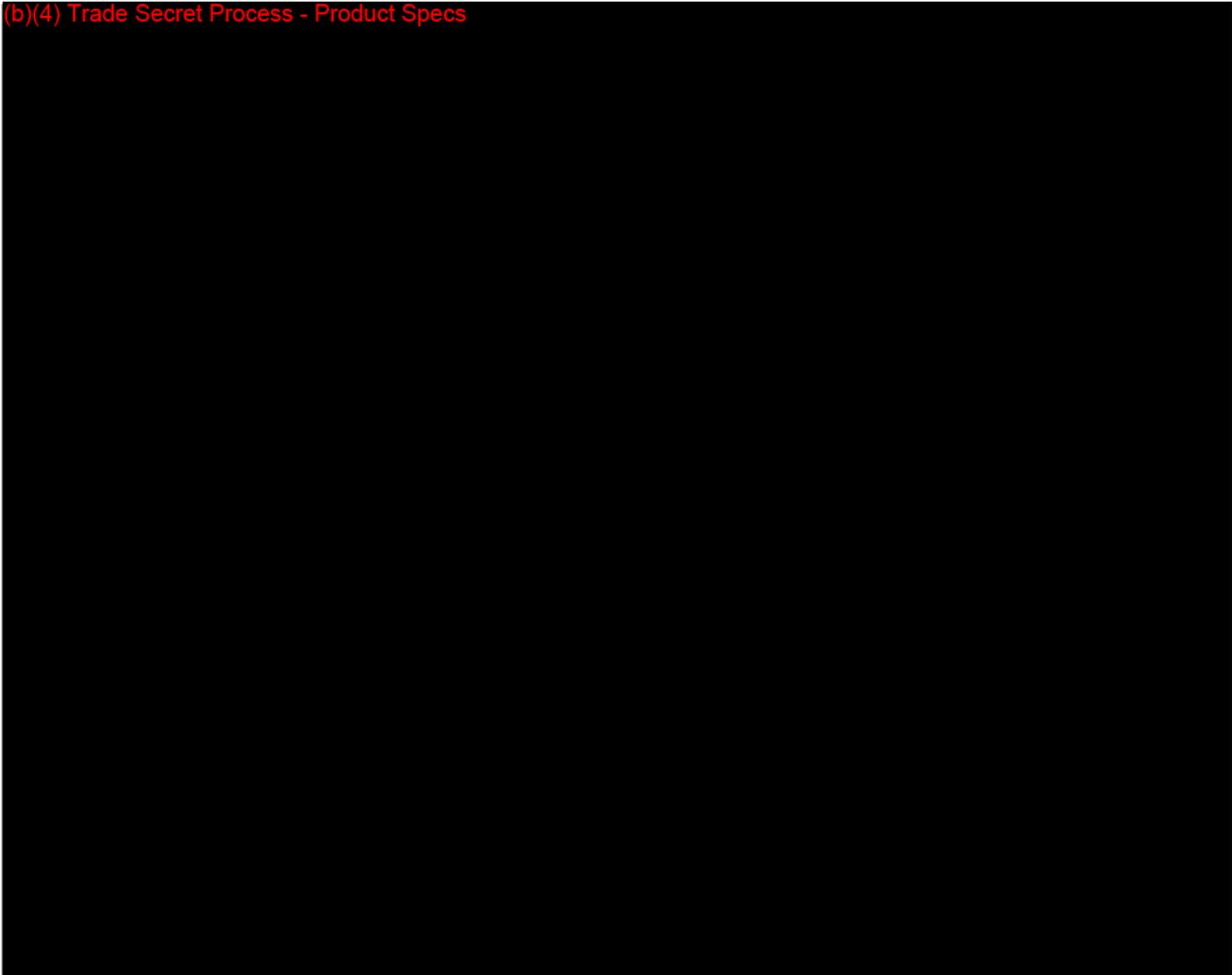
K093

Attention: Michel Janda

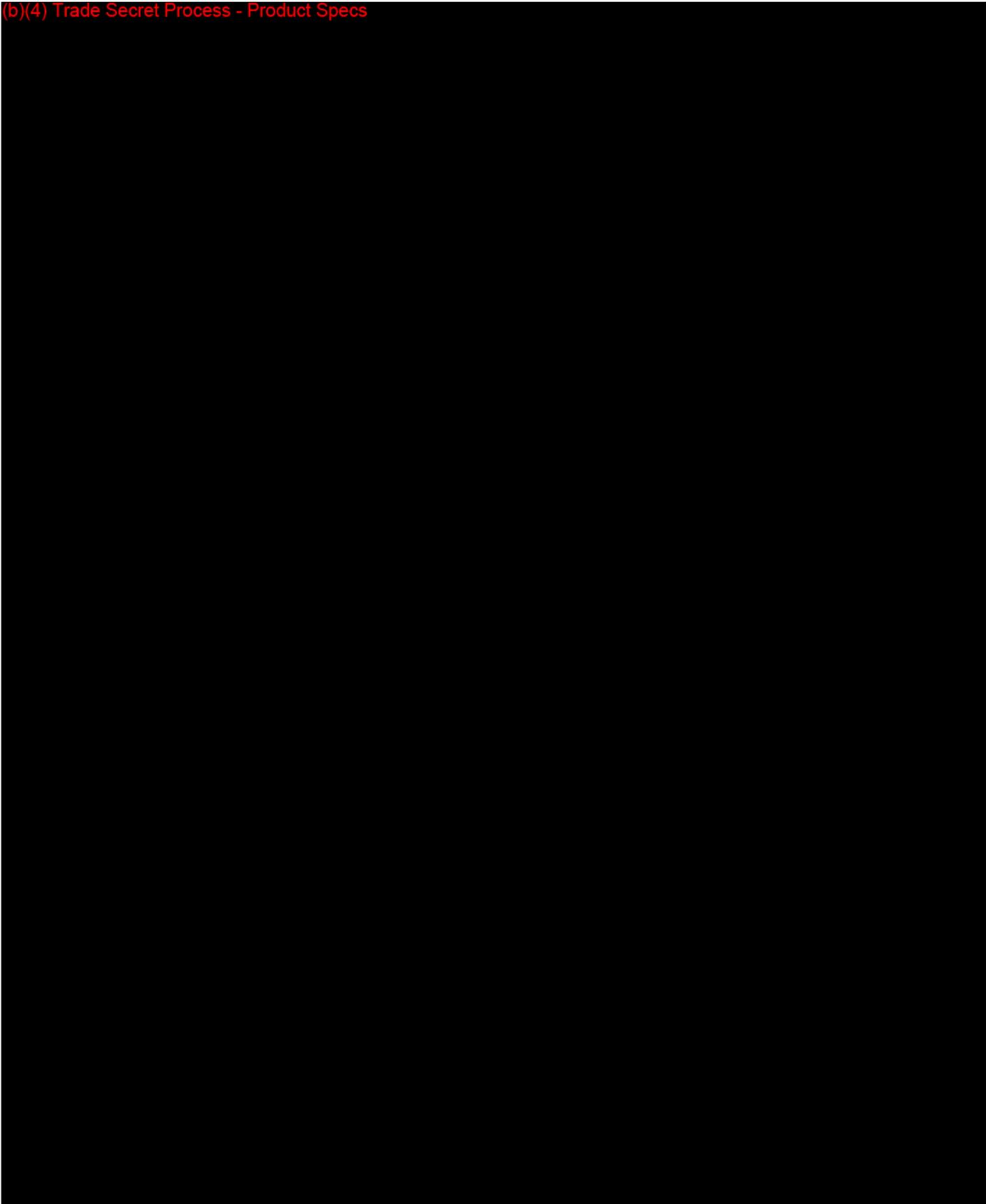
Re: Stryker Arthroscope, K093677.

Dear Mr. Michel Janda,

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

Sincerely,



Shibir Desai

Regulatory Affairs Analyst
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95136
t: (408) 754-2540
Shibir.Desai@stryker.com

ATTACHMENT 1

TAB 1

K093677



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Endoscopy

Device Name

Proprietary Name: Stryker Arthroscope
 Common and Usual Names: Stryker Arthroscope
 Classification Name: Arthroscope (21 CFR § 888.1100, Product Code HRX)

Intended Use: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

Device Description: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. The Stryker Arthroscope is a long tube containing a series of lenses. At the distal end, an objective lens captures the image of the object. Lens along the rod relay the image. At the proximal end, a proximal coupling lens relays the image to a CCD (Camera).

The Stryker Arthroscopes come in various diameters including 1.9mm, 2.3mm, 2.7mm, and 4.0mm. Larger size arthroscopes are used for general viewing, while smaller diameter arthroscopes are used for restricted surgical sites. The Stryker Arthroscopes come in several directions of view including, 0°, 30°, 45°, 70°. The direction of view enables viewing of different parts. Materials of the Arthroscope include stainless steel, titanium, PEEK, Glass, and Sapphire.

Technological Characteristics: The Stryker Arthroscopes are substantially equivalent in construction and materials to the predicate Henke Sass Wolf Arthroscopes (K080560).

	Proposed Device	Predicate Device	Equivalence	Impact on Safety and Effectiveness
Device	Stryker Arthroscope	HSW Arthroscope		
Technological Characteristics (Design)				
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°	Different	The differences in the Field of view do not affect the safety and efficacy of the device.
Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°	Same	N/A

Outer Diameter	4mm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm	Same	N/A
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm	Different	The lengths are within the range of the predicate. The differences in the length do not affect the safety and efficacy of the device.
Single Use or Reusable	Reusable	Reusable	Same	Equivalent
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics	Same	N/A

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Contact:



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Feb 25, 2010

Date:

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TAB 2

