



SEP 15 2011

### 510(k) Summary

**Date Prepared:** June 22, 2011  
**Submitter Information:** Entellus Medical, Inc.  
 6705 Wedgwood Court, North  
 Maple Grove, MN 55311

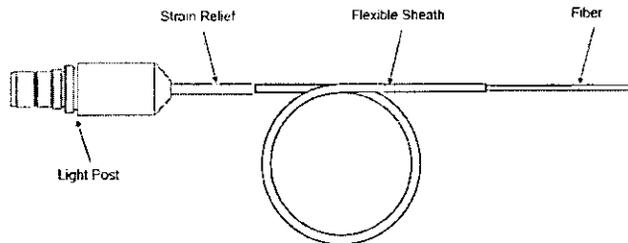
**Establishment Registration:** 3006345872

**Contact Information:** Karen E. Peterson  
 Vice President Clinical, Regulatory and Quality  
 (763) 463-7066  
[kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)

**Device Information:**  
**Trade Name:** PathAssist Light Fiber  
**Common Name:** Sinus Guidewire  
**Classification Regulation:** 21 CFR 874.4420  
**Classification Name:** ENT Manual Surgical Instrument  
**Classification Panel:** ENT  
**Device Classification:** Class I  
**Product Code:** LRC

**Predicate Device:**  
 Acclarent Relieva Luma Sinus Illumination System [K071845]

**Device Description:**  
 The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. The Light Fiber is provided sterile and is for single use only. It comes with a male tuohy borst adapter, which allows the device to be secured within compatible working lumen instruments. The Light Fiber is also compatible with standard light post adapters and light cables.



PathAssist Light Fiber

**Indication for Use**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

**Contraindications:**

None

**Technological Characteristics:**

The subject device has very similar technological characteristics (i.e., design, function, principle of operation, materials, biocompatibility and sterilization) as the predicate device: Acclarent Relieva Luma Sinus Illumination System [K071845].

Both the subject device and predicate device [K071845] are flexible devices that transmit light from the proximal to distal tip of the device via Light Fibers that can be seen via transillumination. Both devices can be connected to a standard light source via a light cable and an adapter.

Both the subject and predicate device [K071845] are sterilized using Ethylene Oxide (EtO), validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of  $10^{-6}$ . Both devices are provided sterile, are for single use only, and are biocompatible per ISO 10993-1.

**Substantial Equivalence:**

The intended use and indications for use of the subject device are the same as the predicate device [Relieva Luma Sinus Illumination System, K071845]. The technological characteristics of the subject device are very similar to the predicate device [K071845], including: design, function, principle of operation, materials, biocompatibility and sterilization.

**Performance Data:**

Performance testing of the PathAssist Light Fiber consisted of biocompatibility testing, design verification testing, packaging, sterilization, shelf life and simulated use in a cadaver model. Design verification testing included functional and mechanical testing, and compatibility testing. Animal and clinical data were not submitted. Performance testing showed that the device meets design specifications and performed as intended.

**Conclusion**

In conclusion, the device is substantially equivalent based on a comparison of intended use, indications for use, and technological characteristics. The device is safe and effective for its intended use.



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

Entellus Medical, Inc.  
% Ms. Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
6705 Wedgewood Court North  
Maple Grove, MN 55311

Re: K111763  
Trade/Device Name: PathAssist Light Fiber  
Regulation Number: 21 CFR 874.4420  
Regulation Name: ENT manual surgical instrument  
Regulatory Class: Class I  
Product Code: LRC  
Dated: August 11, 2011  
Received: August 12, 2011

SEP 15 2011

Dear Ms. Peterson:

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.

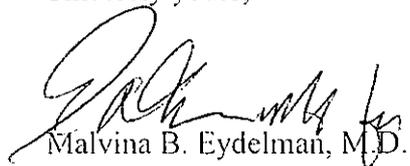
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**6. Indications for Use Statement**

510(k) Number (if known): K111763

**Device Name:** PathAssist Light Fiber

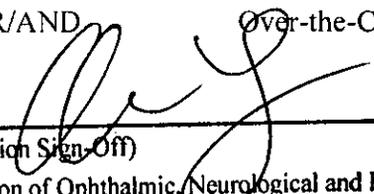
**Indications for Use**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X - OR/AND Over-the-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K111763



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

Entellus Medical, Inc.  
% Ms. Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
6705 Wedgewood Court North  
Maple Grove, MN 55311

Re: K111763  
Trade/Device Name: PathAssist Light Fiber  
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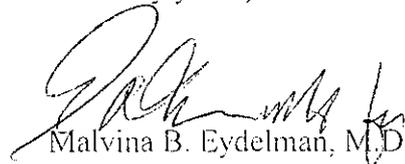
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related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number (if known): K111763

Device Name: PathAssist Light Fiber

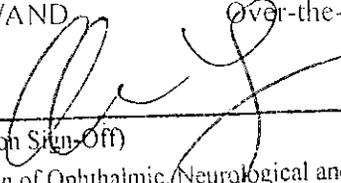
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Concurrence of CDRIH Office of Device Evaluation (ODE)

Prescription Use X - OR/AND Over-the-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K111763



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

August 15, 2011

ENTELLUS MEDICAL, INC.  
6705 WEDGWOOD COURT NORTH  
MAPLE GROVE, MINNESOTA 55311  
ATTN: KAREN E. PETERSON

510k Number: K111763

Product: PATHASSIST LIGHT FIBER

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



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

August 11, 2011

ENTELLUS MEDICAL, INC.  
6705 WEDGWOOD COURT NORTH  
MAPLE GROVE, MINNESOTA 55311  
ATTN: KAREN E. PETERSON

510k Number: K111763

Product: PATHASSIST LIGHT FIBER

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 Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

June 23, 2011

ENTELLUS MEDICAL, INC.  
6705 WEDGWOOD COURT NORTH  
MAPLE GROVE, MINNESOTA 55311  
ATTN: KAREN E. PETERSON

510k Number: K111763

Received: 6/23/2011

Product: PATHASSIST LIGHT FIBER

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

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>.

**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.**

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

ap



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

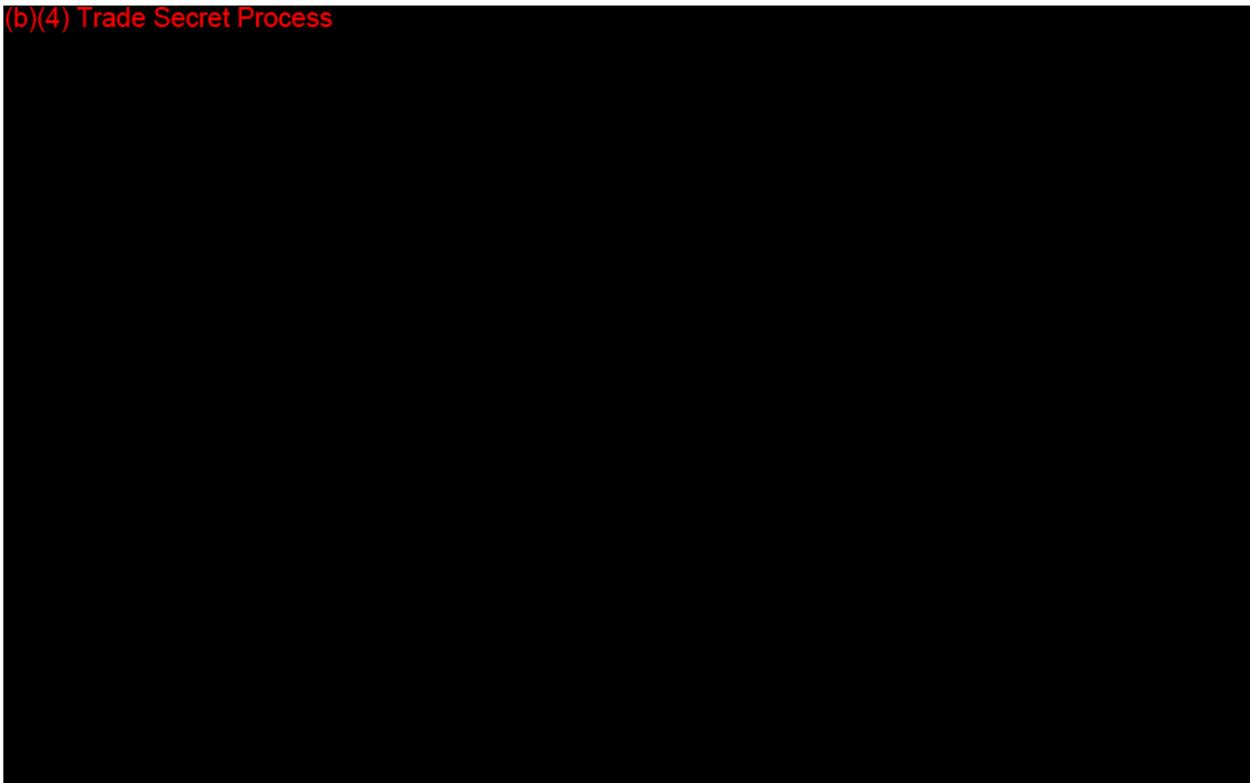
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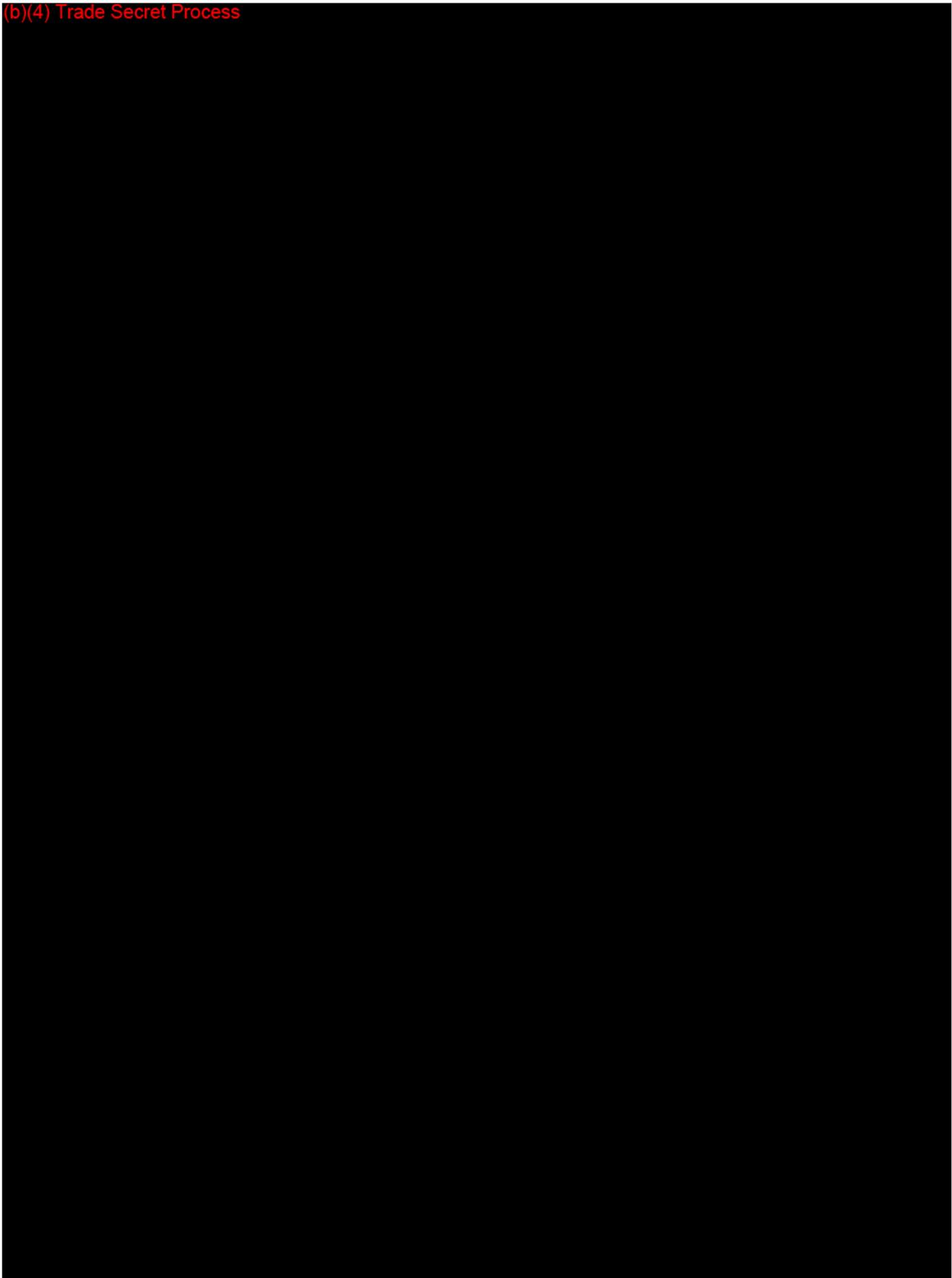
Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require additional information. Please address the following:

(b)(4) Trade Secret Process



(b)(4) Trade Secret Process



“FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment” at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf>

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 additional information 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.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact LT Andrew Yang at (301) 796-6491. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

K111763  
EN/DONED



June 22, 2011

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – W066-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

JUN 23 2011

Received

K33

Re: Traditional 510(k) Notification for PathAssist Light Fiber

Dear Sir or Madam,

Enclosed is a Traditional 510(k) Premarket Notification, submitted in duplicate by Entellus Medical, in accordance with 21CFR Part 807, Subpart E for the PathAssist Light Fiber. The PathAssist Light Fiber is intended to locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

The PathAssist Light Fiber is manufactured at Entellus Medical, 6705 Wedgwood Court North, Maple Grove, MN 55311. Sterilization is completed at STERIS Isomedix Services, 380 90<sup>th</sup> Avenue Northwest, Coon Rapids, MN 55433-5826.

One paper copy and one electronic copy (eCopy) of this submission is provided. The eCopy follows the formatting requirements as per FDA's web instructions and it is an exact duplicate of the paper copy.

**General Information**

Type of Submission	Traditional 510(k)
Basis for Submission	New device
Submitter's name and Address	Entellus Medical 6705 Wedgwood Court North Maple Grove, MN 55311
Contact Person	Karen E. Peterson Vice President Clinical, Regulatory and Quality Tel: 1- (763) 463-7066 Fax: 1- (763) 463-1599 Email: kpeterson@entellusmedical.com

Address - Manufacturing site      Entellus Medical  
 6705 Wedgwood Court North  
 Maple Grove, MN 55311

(b)(4) Trade Secret Process

Common / Usual Name              Sinus Guidewire  
 Trade Name                            PathAssist Light Fiber  
 Classification Regulation          21CFR 874.4420  
 Classification Name                ENT Manual Surgical Instrument  
 Classification Panel                ENT  
 Class                                      Class I  
 Product Code                        LRC

Model Number                        PLF

Identification of Predicate        Acclarent Relieva Luma Sinus Illumination System  
 Devices                                [K071845]

**Design and Use of Device**

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?		√

Some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with Entellus Medical as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

Thank you for your consideration of the information provided in this 510(k) Notification. If you have any questions or need any additional information during your review, please contact me by telephone at 763-463-7066 or 651-398-4341, or by email at [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com).

Sincerely,

A handwritten signature in blue ink that reads "Karen E. Peterson". The signature is written in a cursive style.

Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
Entellus Medical  
Office: 763-463-7066  
Cell: 651-398-4341  
Email: [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)



## Traditional 510(k) Premarket Notification

### PathAssist™ Light Fiber

Date: June 22, 2011

Submitted by:

A handwritten signature in blue ink, reading "Karen E. Peterson", is written over a horizontal line.

Karen E Peterson  
Vice President Clinical, Regulatory and Quality  
Entellus Medical, Inc.  
6705 Wedgwood Court North  
Maple Grove, MN 55311

Entellus Medical Inc. considers all information within this 510(k) notification pertaining to the design of the Device and testing to be confidential. Entellus Medical requests that the information herein be protected as such.

## Table of Contents

<b><u>Section</u></b>	<b><u>Page</u></b>
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## **Attachments**

Attachment 1	Medical Device User Fee Cover Sheet (Form FDA 3601)
Attachment 2	510(k) Cover Letter
Attachment 3	Truthful and Accuracy Statement
Attachment 4	Standards Data Report Forms for 510(k)s – FDA 3654
Attachment 5	Engineering Drawing
Attachment 6	Information & IFU on Predicate Device: Acclarent Relieva Luma Sinus Illumination System [K071845]
Attachment 7	Packaging Labels
Attachment 8	Instructions for Use (IFU)
Attachment 9	Biocompatibility Results
Attachment 10	Dimensional and Strength DV Protocol and Report
Attachment 11	Light Intensity DV Protocol and Report
Attachment 12	Heat Dissipation Mapping Evaluation and DV Protocol and Report
Attachment 13	Device Compatibility DV Protocol and Report
Attachment 14	Packaging DV Protocol and Report
Attachment 15	Simulated Use in a Cadaver Model Protocol and Report

**2. Medical Device User Fee Cover Sheet (Form FDA 3601)**

The Medical Device User Fee Cover Sheet is in Attachment 1.

### **3. CDRH Premarket Review Submission Cover Sheet**

The CDRH Premarket Review Submission Cover Sheet is on the following pages.

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

Form Approval  
OMB No. 9010-0120

Date of Submission  
**June 22, 2011**

User Fee Payment ID Number  
**(b)(4) Trade Secret**  
P

FDA Submission Document Number (if known)

**SECTION A****TYPE OF SUBMISSION**

<b>PMA</b>	<b>PMA &amp; HDE Supplement</b>	<b>PDP</b>	<b>510(k)</b>	<b>Meeting</b>
<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	<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	<input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<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	<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 ( <i>specify</i> ):
<b>IDE</b>	<b>Humanitarian Device Exemption (HDE)</b>	<b>Class II Exemption Petition</b>	<b>Evaluation of Automatic Class III Designation (De Novo)</b>	<b>Other Submission</b>
<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> 513(g) <input type="checkbox"/> Other ( <i>describe submission</i> ):

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 <b>Entellus Medical, Inc.</b>		Establishment Registration Number (if known) <b>3006345872</b>	
Division Name (if applicable)		Phone Number (including area code) <b>(763) 463-7056</b>	
Street Address <b>6705 Wedgwood Court North</b>		FAX Number (including area code) <b>(763) 463-1599</b>	
City <b>Maple Grove</b>	State / Province <b>MN</b>	ZIP/Postal Code <b>55311</b>	Country <b>USA</b>
Contact Name <b>Karen E. Peterson</b>			
Contact Title <b>Vice President, Clinical, Regulatory and Quality</b>		Contact E-mail Address <b>kpeterson@entellusmedical.com</b>	

**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/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

**SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE**

<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 ( <i>specify below</i> )  Other ( <i>specify below</i> )	<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"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<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 ( <i>specify</i> ):		

**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 Request for Removal of Applicant Hold	<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"/> 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"/> Repose 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 Manufacturer
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D3 REASON FOR SUBMISSION - 510(k)**

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

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, <b>safety and effectiveness information</b> <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	<b>KAM</b>	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	<b>K071845</b>	<b>Relieva Luma Sinus Illumination System</b>	<b>Acclarent, Inc.</b>
2			
3			
4		6	6

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
**Common name: Sinus Guidewire**  
**Classification name: ENT Manual Surgical Instrument**

	Trade or Proprietary or Model Name for This Device	Model Number
1	<b>PathAssist Light Fiber</b>	<b>1 PLF</b>
2		<b>2</b>

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

1	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 <b>LRC</b>	C.F.R. Section (if applicable) <b>21 CFR 874.4420</b>	Device Class <input checked="" type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel <b>ENT</b>		

Indications (from labeling)  
  
**To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.**

<p><i>Note:</i> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.</p>	<p>FDA Document Number <i>(if known)</i></p>
---	--

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

**(b)(4) Trade Secret Process**

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

**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	11135-1	ISO	Sterilization of health care products - ethylene oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices		2007
2	10993-7	ISO	Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals		2008
3	10993-10	ISO	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity		2010
4	10993-1	ISO	A Biological evaluation of medical devices -- Part 1: Evaluation and testing		2009
5	11607	ISO	Packaging for terminally sterilized medical devices – Part 1 & Part 2		2006
6	D4169	ASTM	Standard Practice for Performance Testing of Shipping Containers and Systems		2009
7	F1980-07	ASTM	Standard guide for accelerated aging of sterile barrier systems for medical devices		2007
8	F88-00	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials.		2009
9	F2096	ASTM	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test).		2004
10					
11					

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:

Food and Drug Administration  
CDRH (HFZ-342)  
9200 Corporate Blvd.  
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*

#### 4. 510(k) Screening Checklist

##### SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: \_\_\_\_\_

The cover letter clearly identifies the type of 510(k) submission as:

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

##### Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	Section 5 & Attachment 2	
Table of Contents.	Section 1	
Truthful and Accurate Statement.	Section 8 & Attachment 3	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Sections 3,5	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Sections 3,5	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Section 15	
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 6	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Section 14	
510(k) Summary or 510(k) Statement.	Section 7	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Section 13	
Identification of legally marketed predicate device. *	Sections 3,5, 7, 14	
Compliance with performance standards. [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA	
Class III Certification and Summary. **	Section 9	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	Section 10	
510(k) Kit Certification ***	NA	

\* - May not be applicable for Special 510(k)s.

\*\* - Required for Class III devices, only.

\*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

**Section 2: Required Elements for a SPECIAL 510(k) submission:**

	<b>Present</b>	<b>Inadequate or Missing</b>
Name and 510(k) number of the submitter's own, unmodified predicate device.	NA	
A description of the modified device and a comparison to the sponsor's predicate device.	NA	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	NA	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	NA	
A Design Control Activities Summary that includes the following elements (a-c):	NA	
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	NA	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	NA	
c. A Declaration of Conformity with design controls that includes the following statements:	NA	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	NA	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	NA	

*Items with checks in the "Present or Adequate" column do not require additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

**Passed Screening** \_\_\_\_ Yes \_\_\_\_ No

**Reviewer:** \_\_\_\_\_

**Concurrence by Review Branch:** \_\_\_\_\_

**Date:** \_\_\_\_\_

The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

Required Elements for a Declaration of Conformity to a Recognized Standard  
(SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS)

Required Element	Present	Inadequate or Missing
a. An identification of the applicable recognized consensus standards that were met.	NA	
b. A statement, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below.	NA	
c. An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).	NA	
d. An identification, for each consensus standard, of any requirements that were not applicable to the device.	NA	
e. A specification of any deviations from each applicable standard that were applied.	NA	
f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.	NA	
g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.	NA	

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):**

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Section 17	
b) Sterilization and expiration dating information:	Section 16	
i) sterilization process	Section 16	
ii) validation method of sterilization process	Section 16	
iii) SAL	Section 16	

iv) packaging	Section 16	
v) specify pyrogen free	Section 16	
vi) ETO residues	Section 16	
vii) radiation dose	NA	
c) Software Documentation:	NA	

*Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.*

Passed Screening \_\_\_\_ Yes \_\_\_\_ No

Reviewer: \_\_\_\_\_

Concurrence by Review Branch: \_\_\_\_\_

Date: \_\_\_\_\_

The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

## **5. Cover Letter**

The 510(k) Cover Letter is in Attachment 2.

**6. Indications for Use Statement**

510(k) Number (if known): \_\_\_\_\_

**Device Name:** PathAssist Light Fiber

**Indications for Use**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

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

\_\_\_\_\_  
Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use   X   - OR/AND Over-the-Counter Use \_\_\_\_\_



## 510(k) Summary

**Date Prepared:** June 22, 2011

**Submitter Information:** Entellus Medical, Inc.  
6705 Wedgwood Court, North  
Maple Grove, MN 55311

**Establishment Registration:** 3006345872

**Contact Information:** Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
(763) 463-7066  
[kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)

**Device Information:**

**Trade Name:** PathAssist Light Fiber

**Common Name:** Sinus Guidewire

**Classification Regulation:** 21 CFR 874.4420

**Classification Name:** ENT Manual Surgical Instrument

**Classification Panel:** ENT

**Device Classification:** Class I

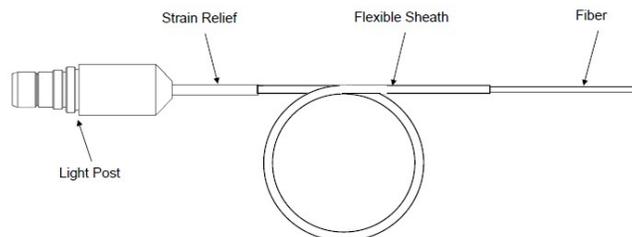
**Product Code:** LRC

### Predicate Device:

Acclarent Relieva Luma Sinus Illumination System [K071845]

### Device Description:

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. The Light Fiber is provided sterile and is for single use only. It comes with a male tuohy borst adapter, which allows the device to be secured within compatible working lumen instruments. The Light Fiber is also compatible with standard light post adapters and light cables.



PathAssist Light Fiber

**Indication for Use**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

**Contraindications:**

None

**Technological Characteristics:**

The subject device has very similar technological characteristics (i.e., design, function, principle of operation, materials, biocompatibility and sterilization) as the predicate device: Acclarent Relieva Luma Sinus Illumination System [K071845].

Both the subject device and predicate device [K071845] are flexible devices that transmit light from the proximal to distal tip of the device via Light Fibers that can be seen via transillumination. Both devices can be connected to a standard light source via a light cable and an adapter.

Both the subject and predicate device [K071845] are sterilized using Ethylene Oxide (EtO), validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of  $10^{-6}$ . Both devices are provided sterile, are for single use only and are biocompatible per ISO 10993-1.

**Substantial Equivalence:**

The intended use and indications for use of the subject device are the same as the predicate device [Relieva Luma Sinus Illumination System, K071845]. The technological characteristics of the subject device are very similar to the predicate device [K071845], including: design, function, principle of operation, materials, biocompatibility and sterilization.

**Performance Data:**

Performance testing of the PathAssist Light Fiber consisted of biocompatibility testing, design verification testing, packaging, sterilization, shelf life and simulated use in a cadaver model. Design verification testing included functional and mechanical testing, and compatibility testing. Animal and clinical data were not submitted. Performance testing showed that the device meets design specifications and performed as intended.

**Conclusion**

In conclusion, the device is substantially equivalent based on a comparison of intended use, indications for use, and technological characteristics. The device is safe and effective for its intended use.

## **8. Truthful and Accuracy Statement**

The Truthful and Accuracy Statement is in Attachment 3.

**9. Class III Summary and Certification**

Not applicable. Device is a class I device.

**10. Financial Disclosure / Certification**

Not applicable, no clinical data is submitted with this application.

## 11. Declarations of Conformity and Summary Reports

Consistent with FDA's guidance documents entitled, "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000) and "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), Entellus Medical is including this statement that the device complies with the following recognized consensus standards and FDA guidance:

- Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 30, 2002.
- ISO 11135-1: 2007 Sterilization of health care products - ethylene oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals.
- ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity.
- ISO 10993-1: 2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing.
- ISO 11607: 2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems; & Part 2: Validation requirements for forming sealing and assembly processes.
- ASTM D4169: 2009 Standard practice for performance testing of shipping containers and systems.
- ASTM F1980-07: 2007 Standard guide for accelerated aging of sterile barrier systems for medical devices.
- ASTM F88-00: 2009 Standard test method for seal strength of flexible barrier materials.
- ASTM F2096: 2004 Standard test method for detecting gross leaks in medical packaging by internal pressurization (bubble test).

*Standards Data Report Forms for 510(k)s – FDA 3654*, for the standards listed above are provided in Attachment 4.

## 12. Executive Summary

### 12.1 DEVICE DESCRIPTION

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. The Light Fiber is provided sterile and is for single use only. It is packaged with a commercially available male tuohy borst adapter, which allows the device to be secured within compatible working lumen instruments. The Light Fiber is also compatible with standard light post adapters and light cables.

Refer to *Section 13 Device Description* for a more detailed product description.

### 12.2 INDICATION FOR USE

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

### 12.3 SUBSTANTIAL EQUIVALENCE

The PathAssist Light Fiber (subject device) is substantially equivalent to the predicate device: Acclarent Relieva Luma Sinus Illumination System [K071845].

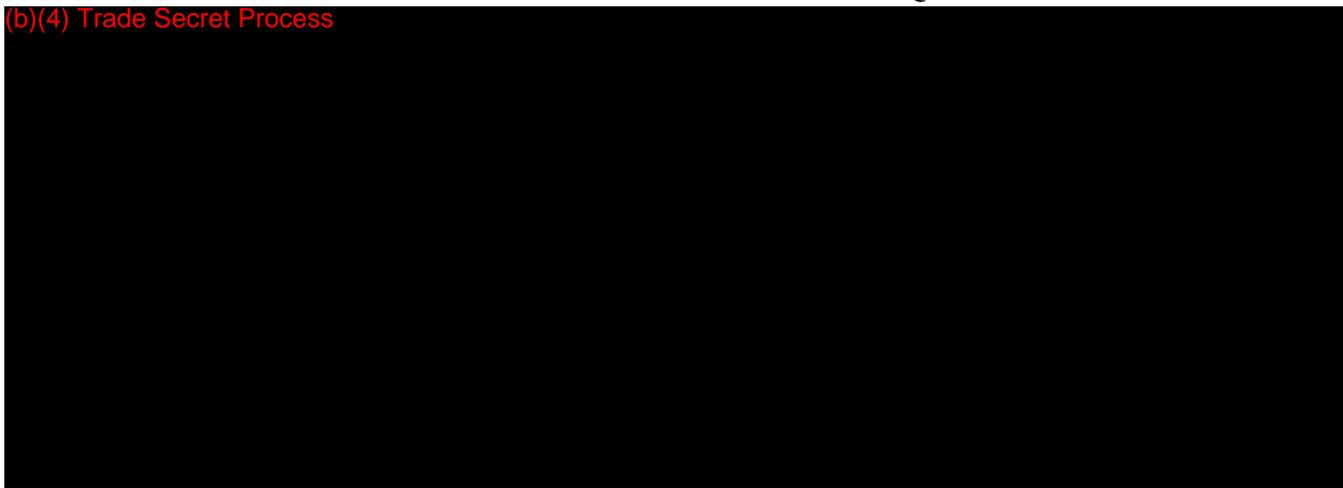
The intended use and indications for use of the subject device are the same as the predicate device [K071845]. The technological characteristics of the subject device are very similar as the predicate device, including design, function, principle of operation, materials, biocompatibility and sterilization.

In summary, we believe that the PathAssist Light Fiber described in this submission is substantially equivalent to the predicate device.

Note: A device comparison table for the subject device and the predicate device is in *Section 14: Substantial Equivalence Discussion*.

### 12.4 PERFORMANCE SPECIFICATIONS & DESIGN REQUIREMENTS

(b)(4) Trade Secret Process



## 12.5 SUMMARY OF PERFORMANCE TESTING

(b)(4) Trade Secret Process



In summary, device performance testing is provided in this 510(k) submission. Performance testing included biocompatibility, functional and mechanical testing, and compatibility testing, packaging, sterilization, shelf life and simulated use in a cadaver model. Animal and clinical data were not submitted. Performance testing showed that the device meets design specifications and performs as intended.

## 12.6 CONCLUSION

In conclusion, the device is substantially equivalent based on a comparison of intended use, indications for use, and technological characteristics. The device is safe and effective for its intended use.

### 13. Device Description

#### 13.1 GENERAL DESCRIPTION

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a nominal fiber working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm. See photo below.

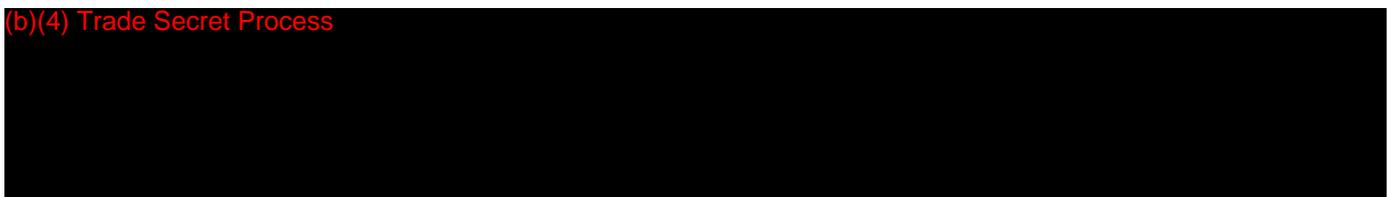
(b)(4) Trade Secret Process



The Light Fiber is provided sterile and is for single use only. It is sterilized with ethylene oxide. It is packaged with a commercially available male tuohy borst adapter, which allows the device to be secured within compatible working lumen instruments. The Light Fiber is also compatible with commonly used standard light post adapters and light cables.

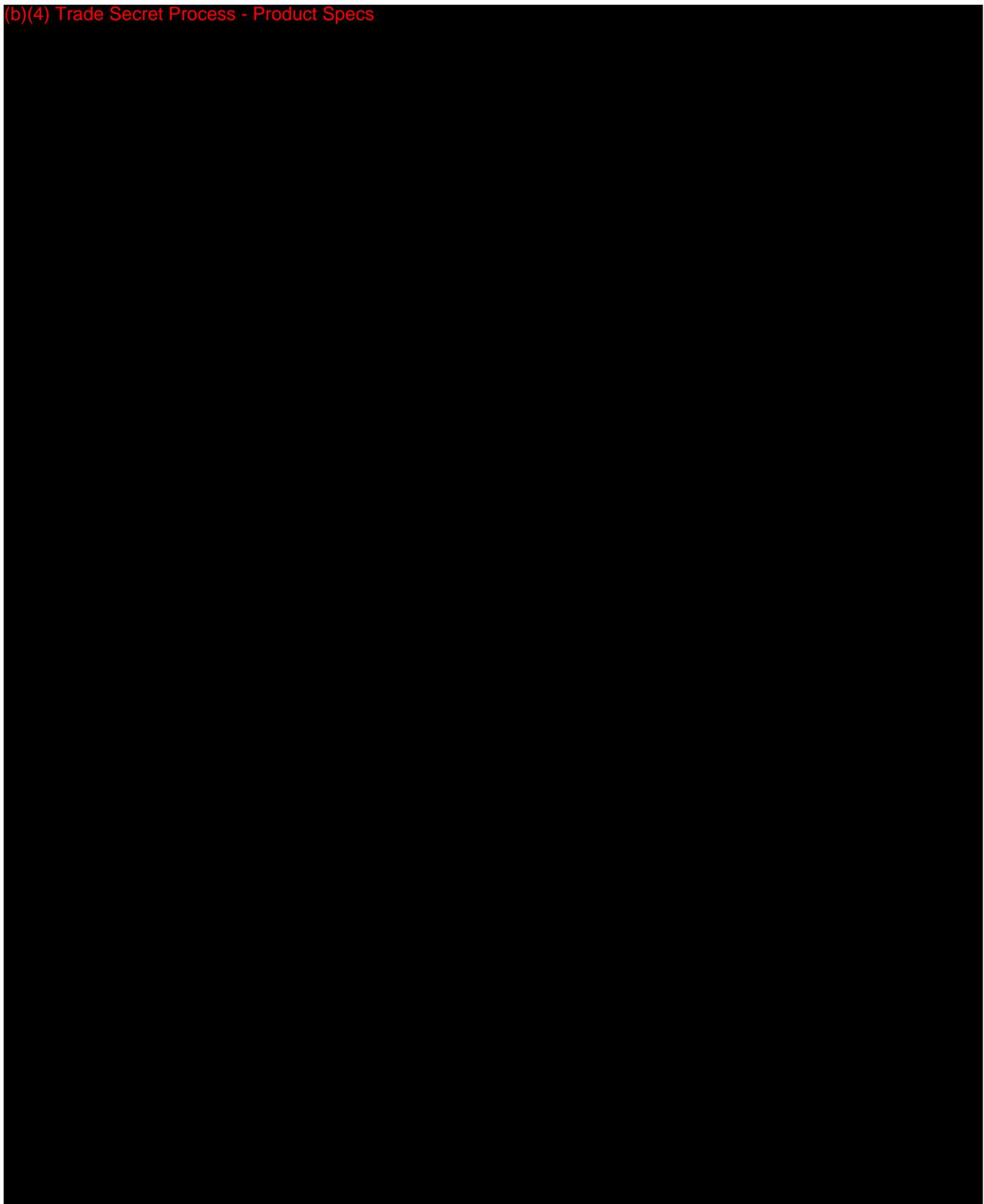
The Light Fiber is intended to locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

(b)(4) Trade Secret Process



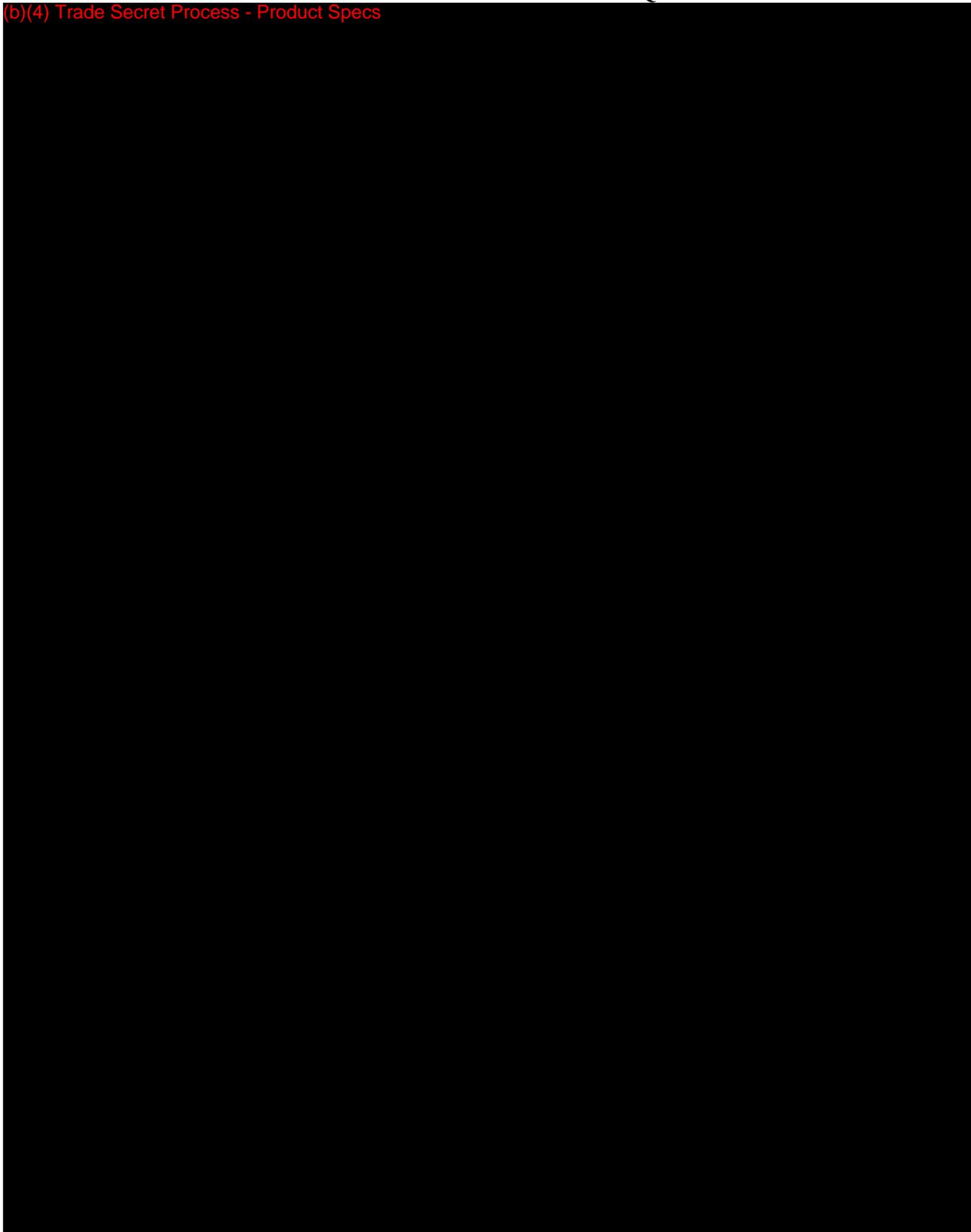
## 13.2 DEVICE MATERIALS

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



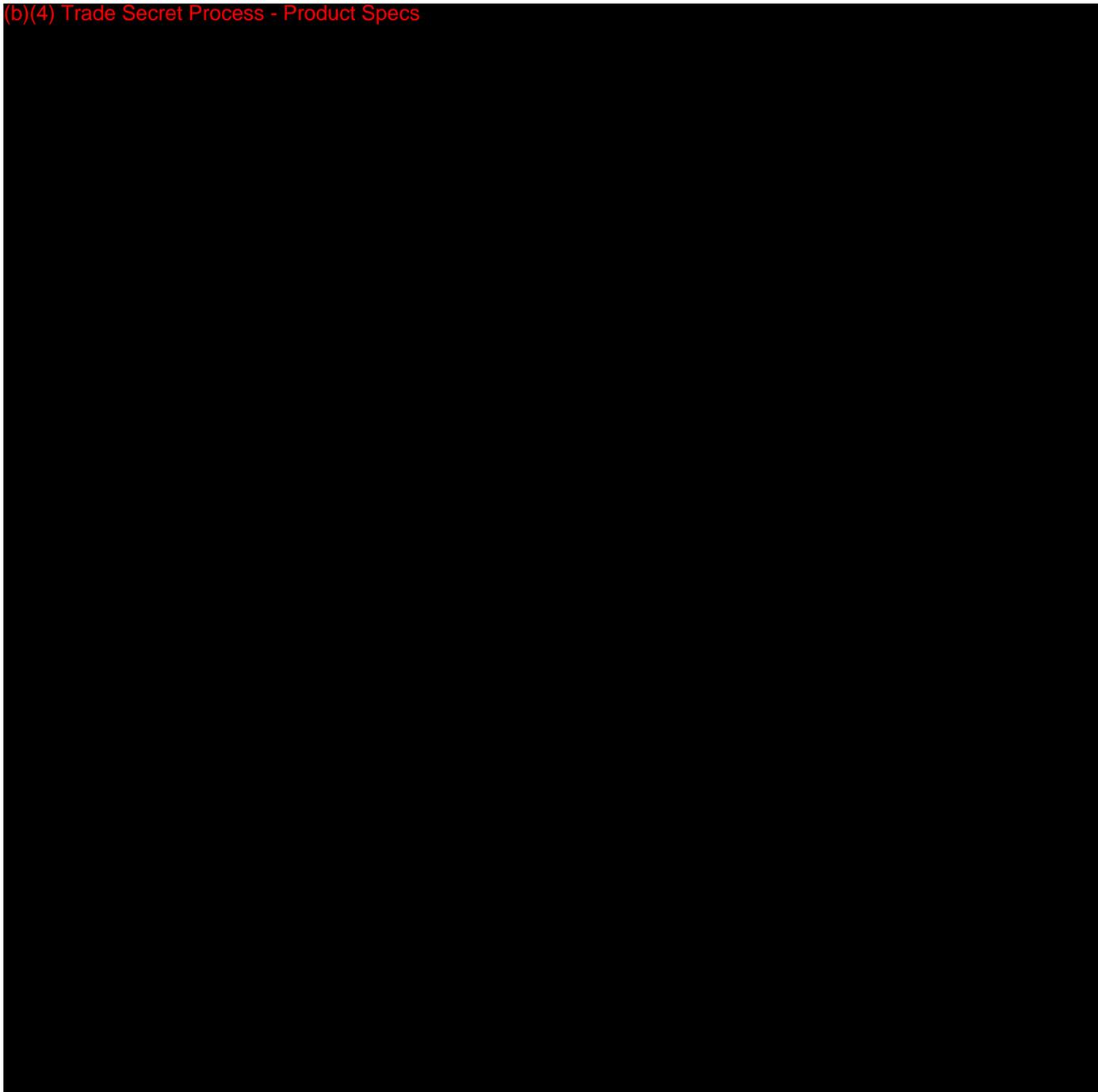
**13.4 PERFORMANCE SPECIFICATIONS & DESIGN REQUIREMENTS**

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



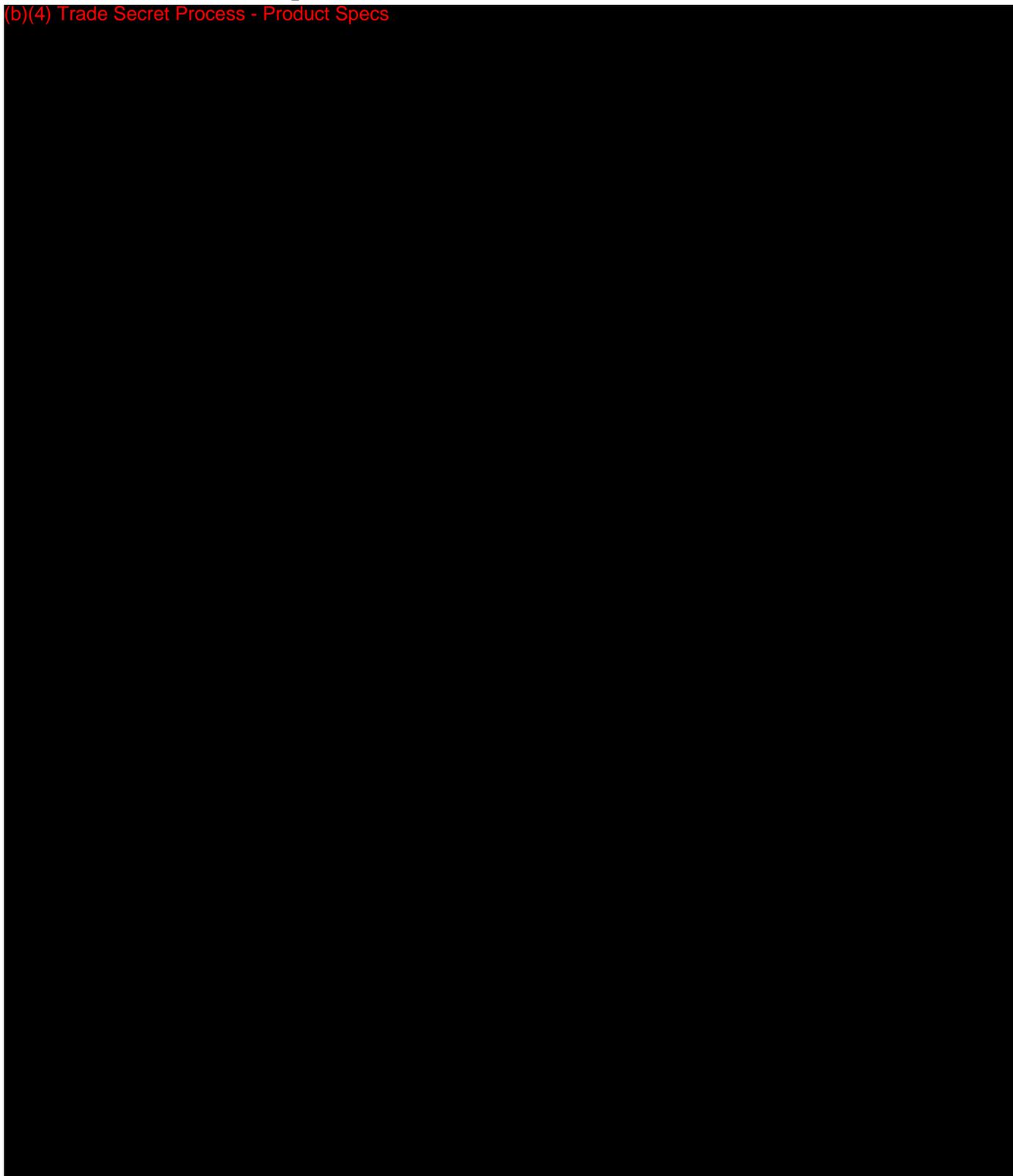
### 13.6 PACKAGING

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

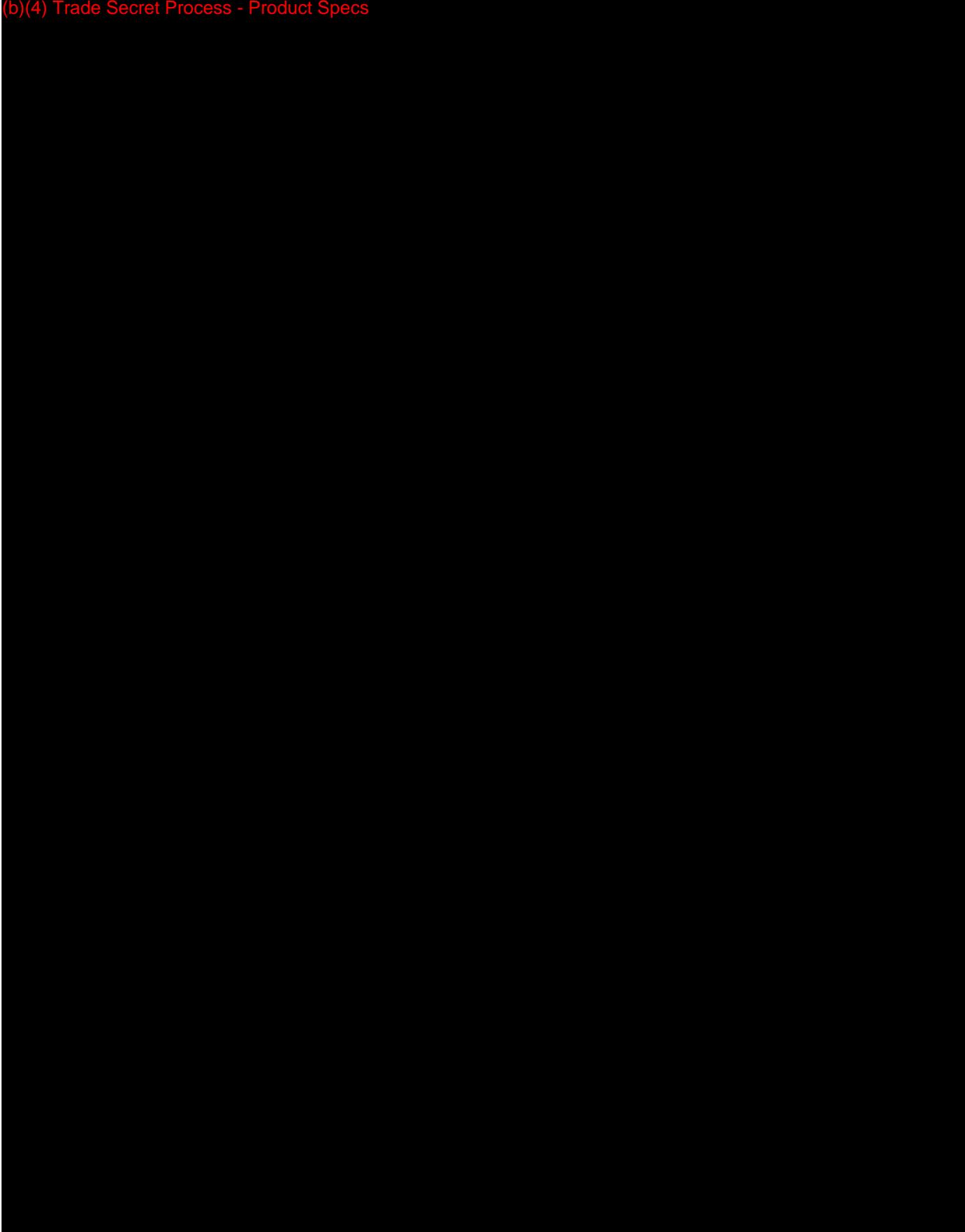


## 14. Substantial Equivalence Discussion

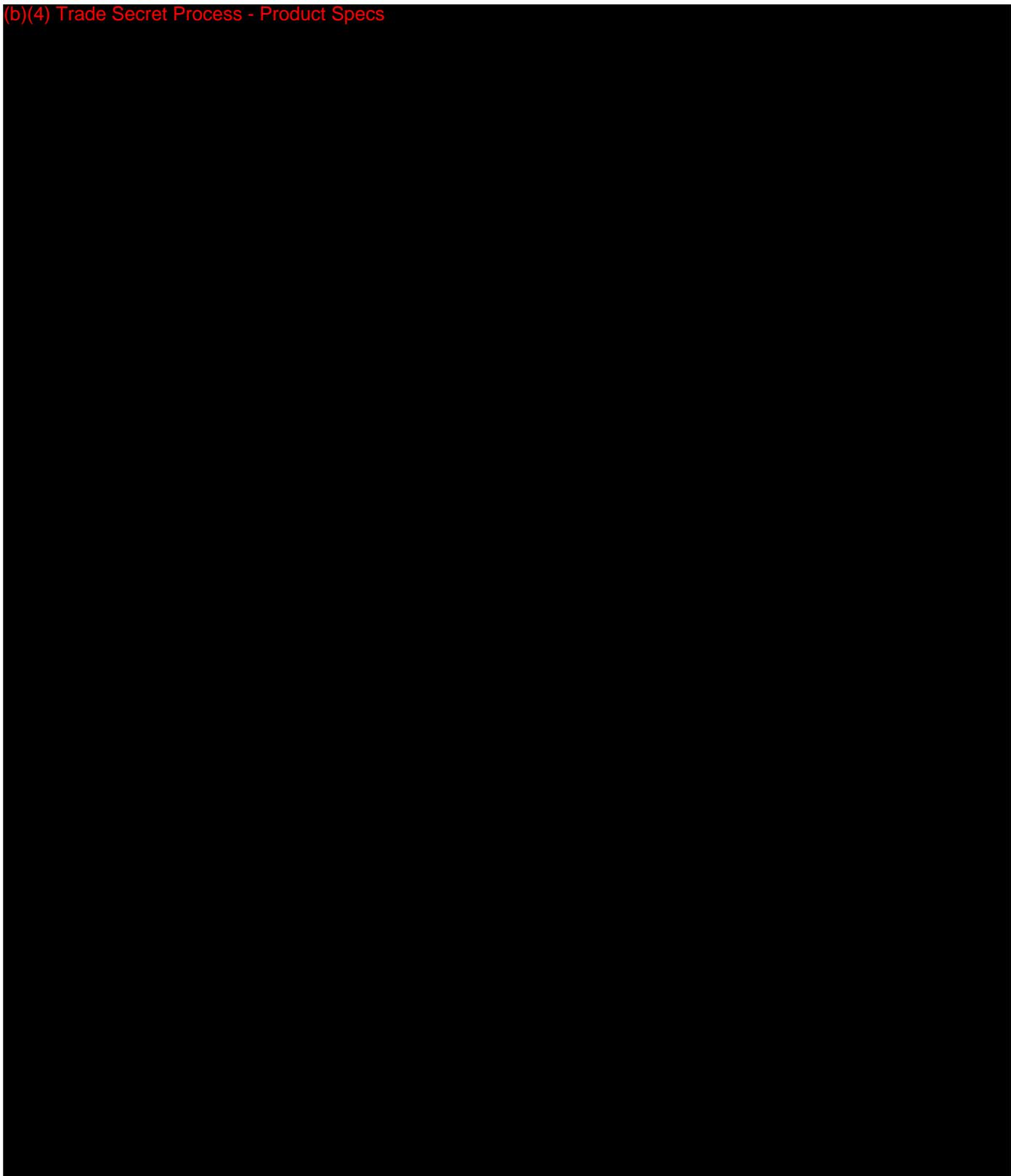
(b)(4) Trade Secret Process - Product Specs



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



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



## **15. Proposed Labeling**

Final draft labeling for the device can be found in the following Attachments:

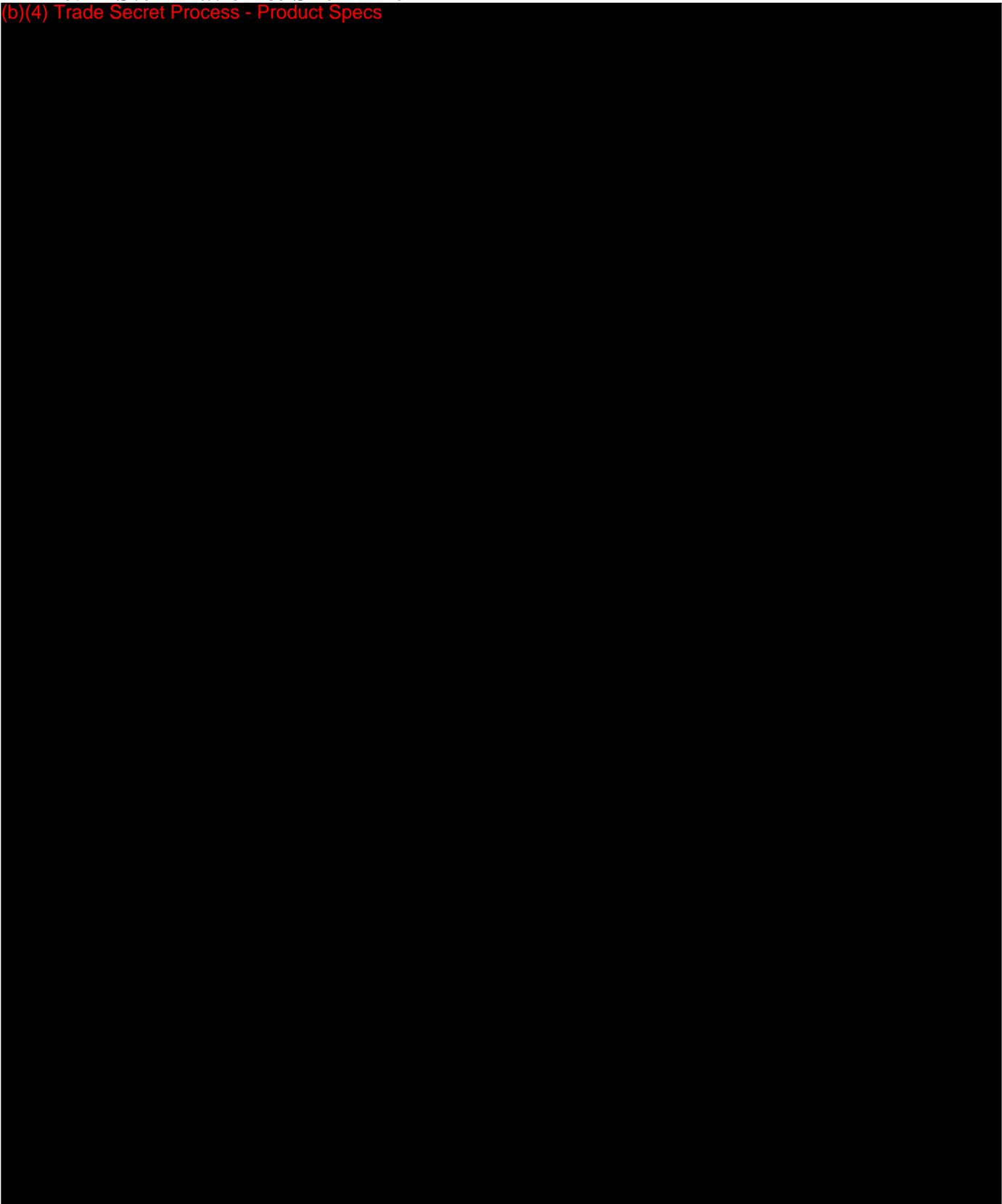
Packaging labels: Attachment 7

Instructions for Use (IFU): Attachment 8

Promotional literature and advertisements have not been developed.

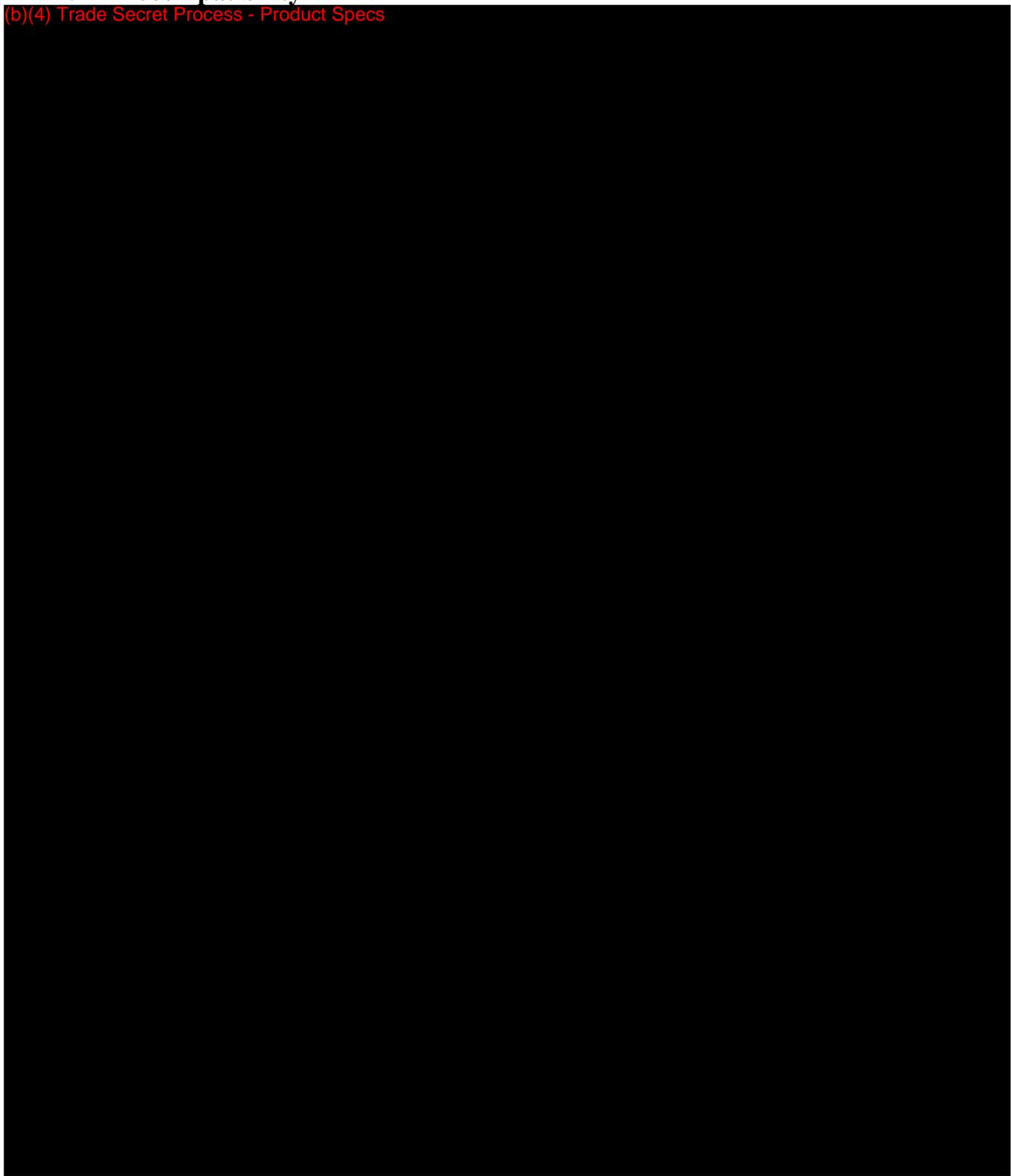
## **16. Sterilization & Shelf Life**

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



## 17. Biocompatibility

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



## **18. Software**

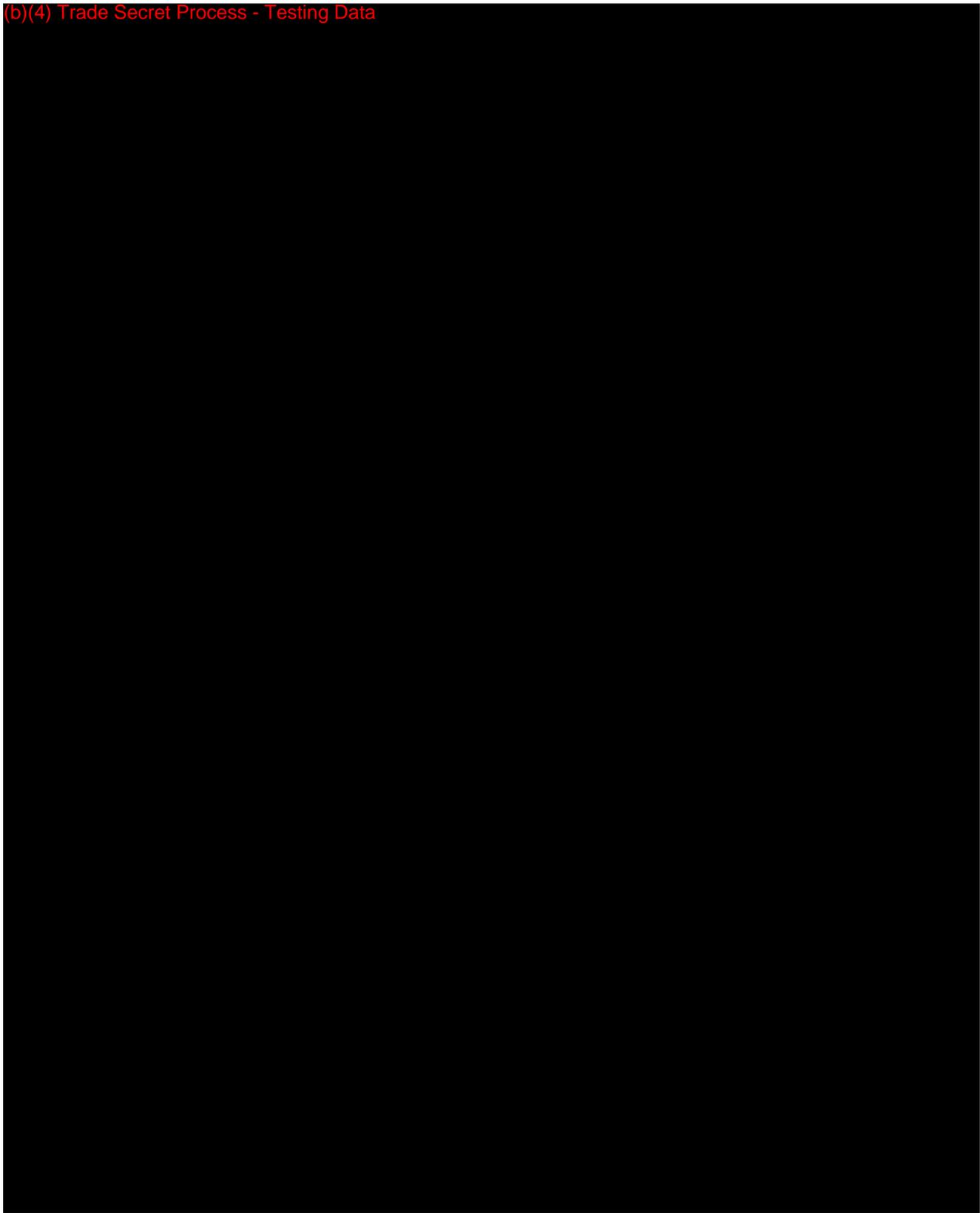
Not applicable. The device does not contain any software.

## **19. EMC and Electrical Safety**

Not applicable. The device does not contain any electrical component nor will it be affected by any electromagnetic emission.

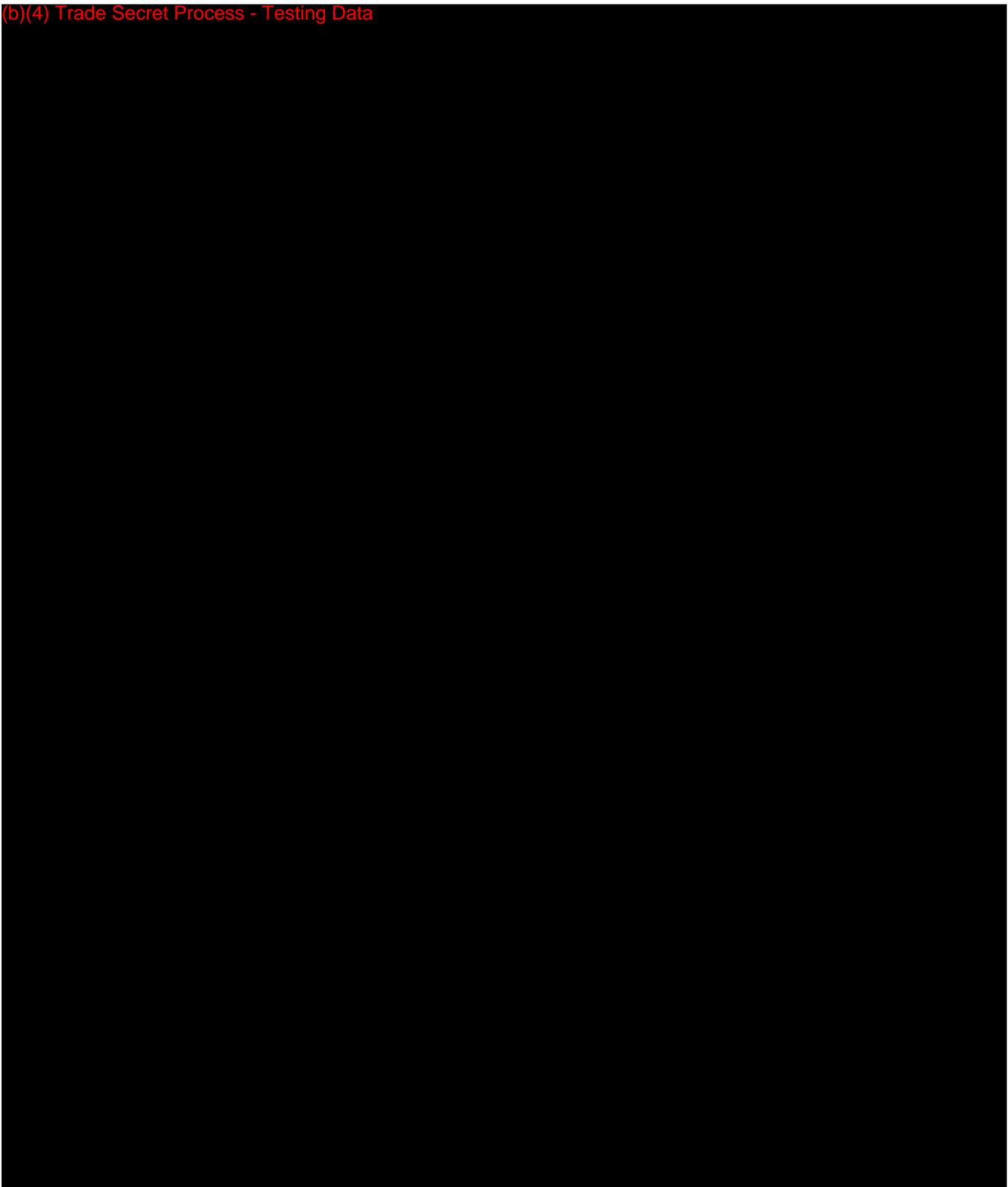
## 20. Performance Testing - Bench

(b)(4) Trade Secret Process - Testing Data

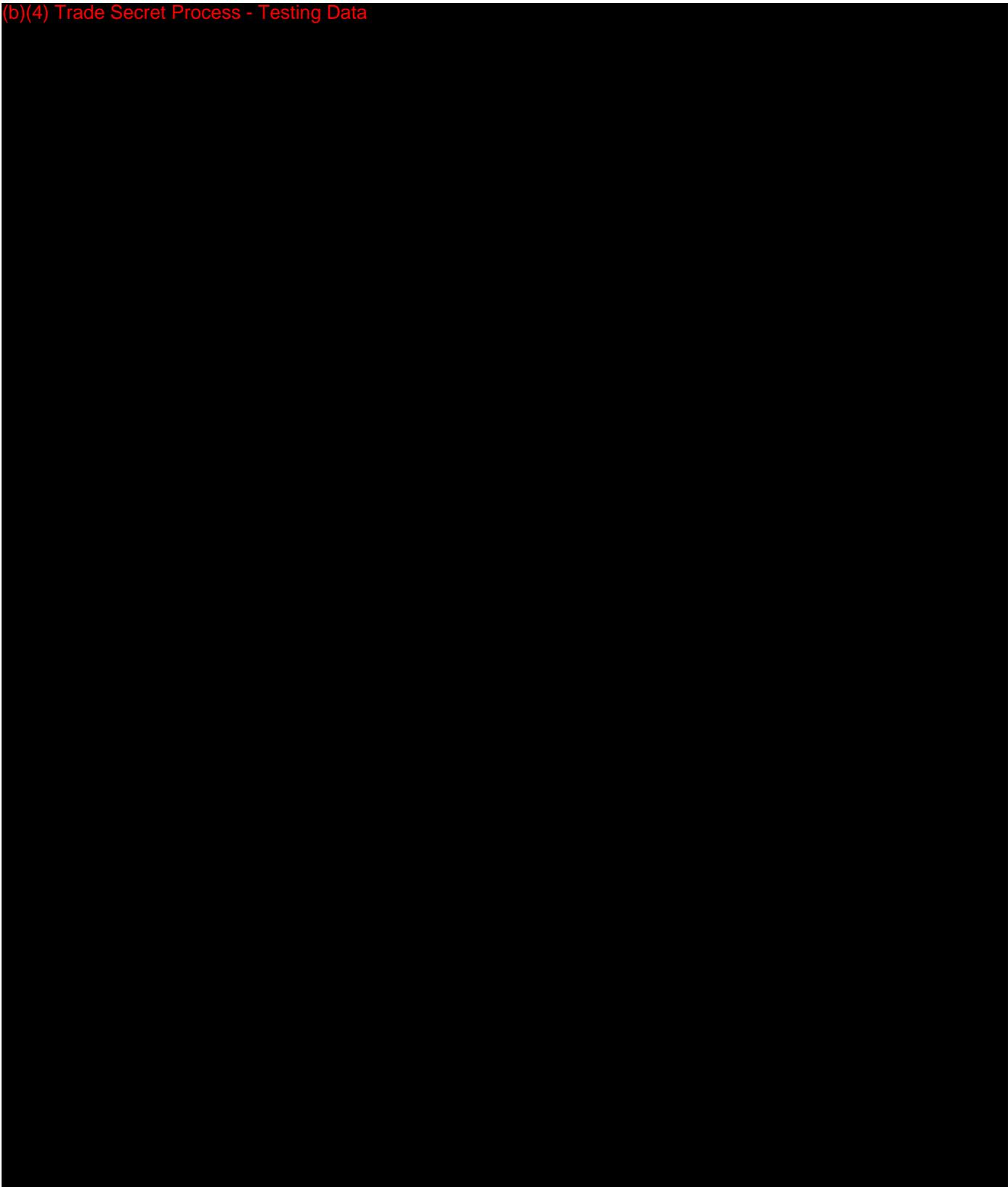


### 20.2.2 Light Intensity Testing

(b)(4) Trade Secret Process - Testing Data

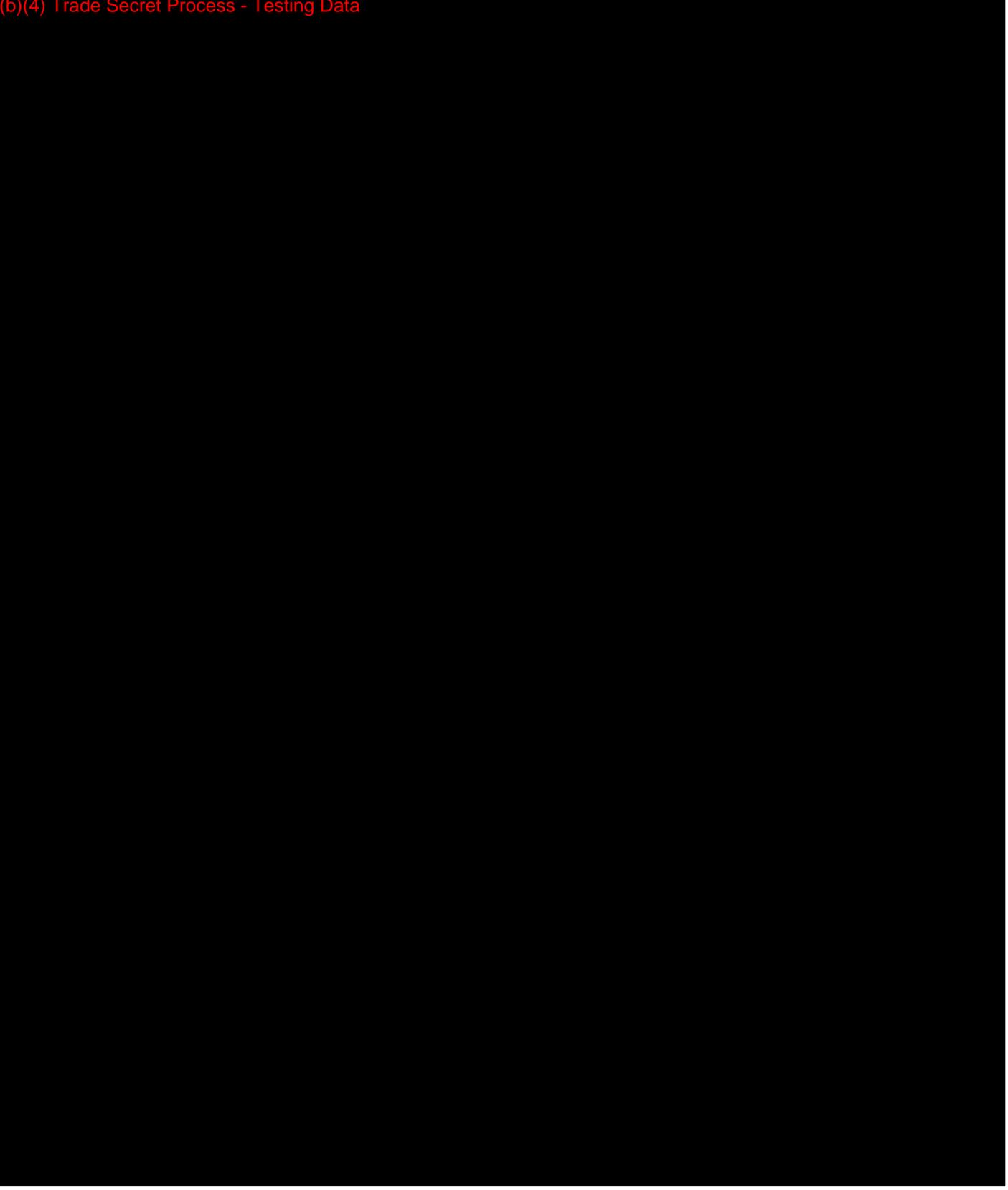


(b)(4) Trade Secret Process - Testing Data



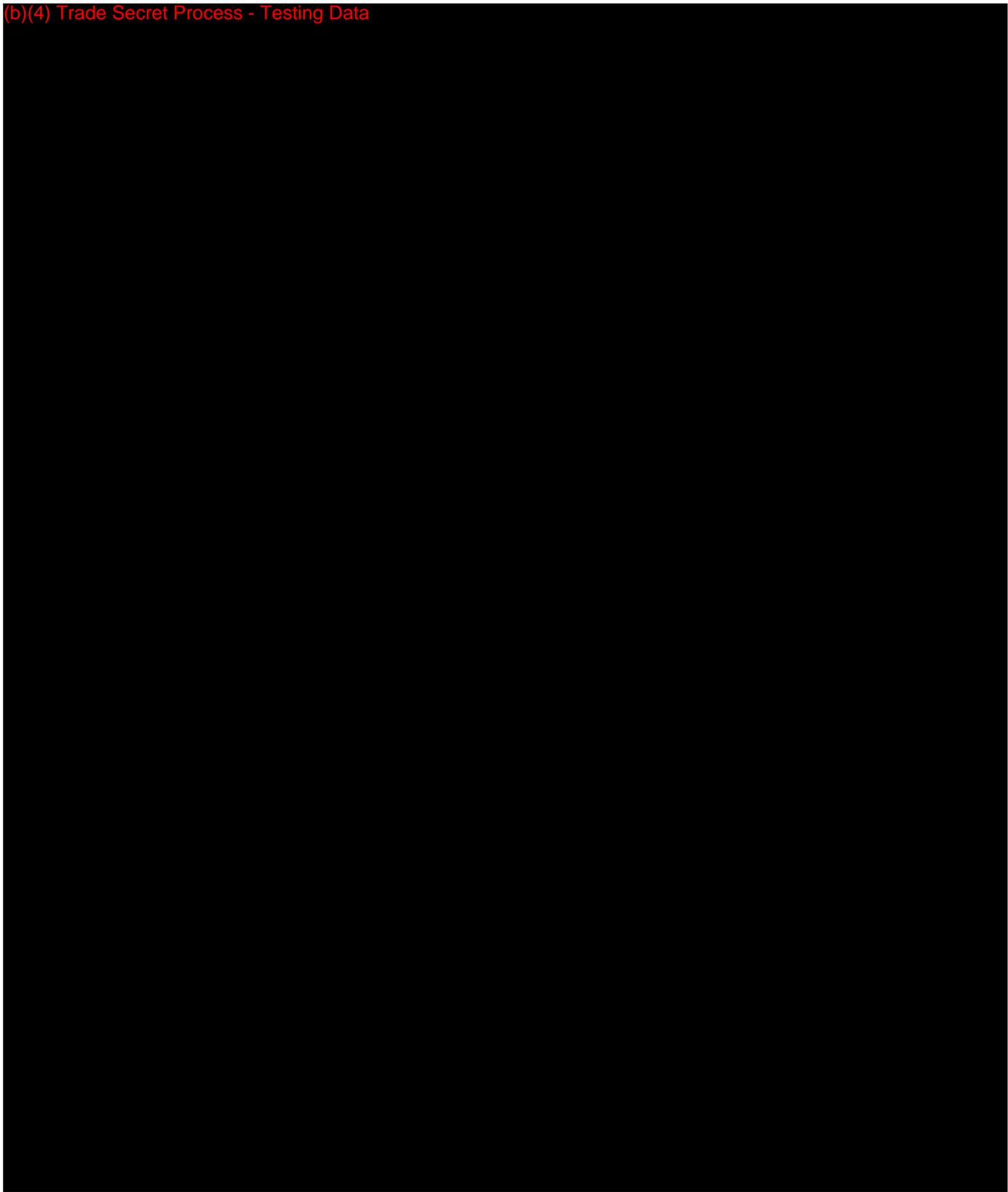
### 20.3 COMPATIBILITY TESTING

(b)(4) Trade Secret Process - Testing Data



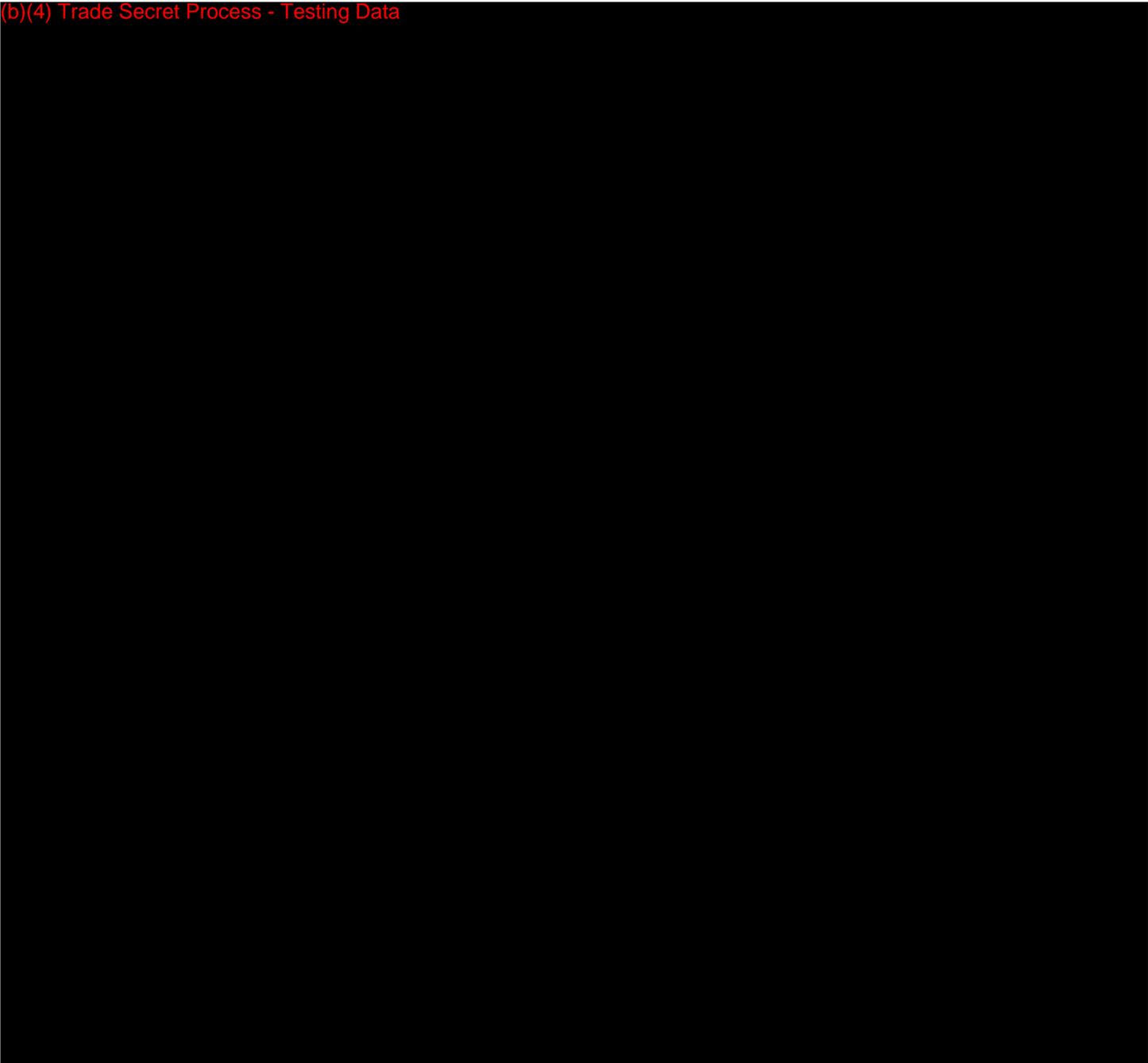
## 20.4 PACKAGING TESTING

(b)(4) Trade Secret Process - Testing Data



## 20.5 SIMULATED USE IN A CADAVER MODEL

(b)(4) Trade Secret Process - Testing Data



## **21. Performance Testing - Animal**

Not Applicable. No animal testing was conducted on the device.

## **22. Performance Testing - Clinical**

Not Applicable. No clinical studies have been conducted on the device.

**23. Kit**

Not Applicable.

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Write the Payment Identification number on your check.	
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: <a href="http://www.fda.gov/oc/mdufma/cover-sheet.html">http://www.fda.gov/oc/mdufma/cover-sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  Entellus Medical Inc. 4055 Deerwood Place Eagan MN 55122 US		2. CONTACT NAME Karen Peterson 2.1 E-MAIL ADDRESS kpeterson@entellusmedical.com 2.2 TELEPHONE NUMBER (include Area code) 763-463-7066 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)			
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: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) 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)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD110237			
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? <input checked="" type="checkbox"/> 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.) <input type="checkbox"/> 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 <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> 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"/> 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 sole purpose of the application is to support conditions of use for a pediatric population <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)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes 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 the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) Trade		18-May-2011	

Form FDA 3601 (01/2007)

"Close Window" [Print Cover sheet](#)



June 22, 2011

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – W066-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

Re: Traditional 510(k) Notification for PathAssist Light Fiber

Dear Sir or Madam,

Enclosed is a Traditional 510(k) Premarket Notification, submitted in duplicate by Entellus Medical, in accordance with 21CFR Part 807, Subpart E for the PathAssist Light Fiber. The PathAssist Light Fiber is intended to locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

The PathAssist Light Fiber is manufactured at Entellus Medical, 6705 Wedgwood Court North, Maple Grove, MN 55311. Sterilization is completed at STERIS Isomedix Services, 380 90<sup>th</sup> Avenue Northwest, Coon Rapids, MN 55433-5826.

One paper copy and one electronic copy (eCopy) of this submission is provided. The eCopy follows the formatting requirements as per FDA's web instructions and it is an exact duplicate of the paper copy.

**General Information**

Type of Submission	Traditional 510(k)
Basis for Submission	New device
Submitter's name and Address	Entellus Medical 6705 Wedgwood Court North Maple Grove, MN 55311
Contact Person	Karen E. Peterson Vice President Clinical, Regulatory and Quality Tel: 1- (763) 463-7066 Fax: 1- (763) 463-1599 Email: <a href="mailto:kpeterson@entellusmedical.com">kpeterson@entellusmedical.com</a>

Address - Manufacturing site      Entellus Medical  
 6705 Wedgwood Court North  
 Maple Grove, MN 55311

(b)(4) Trade Secret Process

Common / Usual Name              Sinus Guidewire  
 Trade Name                            PathAssist Light Fiber  
 Classification Regulation          21CFR 874.4420  
 Classification Name                ENT Manual Surgical Instrument  
 Classification Panel                ENT  
 Class                                      Class I  
 Product Code                        LRC

Model Number                        PLF

Identification of Predicate        Acclarent Relieva Luma Sinus Illumination System  
 Devices                                [K071845]

**Design and Use of Device**

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?		√

Some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with Entellus Medical as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

Thank you for your consideration of the information provided in this 510(k) Notification. If you have any questions or need any additional information during your review, please contact me by telephone at 763-463-7066 or 651-398-4341, or by email at [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com).

Sincerely,

A handwritten signature in blue ink that reads "Karen E. Peterson". The signature is fluid and cursive, with the first letters of each name being capitalized and prominent.

Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
Entellus Medical  
Office: 763-463-7066  
Cell: 651-398-4341  
Email: [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)

## Truthful and Accuracy Statement

**PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT  
[as required by 21 CFR 807.87(j)]**

I certify that, in my capacity as Vice President Clinical, Regulatory and Quality at Entellus Medical, I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.



Date: 6-22-11

---

Karen E. Peterson  
Vice President Clinical, Regulatory and Quality

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 <sup>1</sup>

ISO 11135-1 (2007) Sterilization of health care products - Ethylene oxide - Part 1

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-228

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

<sup>4</sup> 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.

<sup>5</sup> 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>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11135-1 2007 Sterilization of health care products - Ethylene oxide - Part 1

**CONFORMANCE WITH STANDARD SECTIONS\***

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 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.
- ♦ 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.*

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 <sup>1</sup>

ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-279

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

<sup>4</sup> 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.

<sup>5</sup> 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>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3.5	Tolerable contact listies for surface contacting devices or implants	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

Option selected: device shall exhibit negligible irritation pre ISO 10993-10

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

\* 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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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.*

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 <sup>1</sup>

ISO 10993-10:2010, 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 <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 2-152 (2006)

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 10993-10:2010, Biological evaluation of medical devices Part 10 —Tests for irritation and delayed-type hypersensitivity

**CONFORMANCE WITH STANDARD SECTIONS\***

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

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

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 Food and Drug Administration  
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*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 10993-1:2009, A Biological evaluation of medical devices -- Part 1: Evaluation and testing

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # 2-156

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

Is a summary report<sup>4</sup> 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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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-1:2009, A Biological evaluation of medical devices -- Part 1: Evaluation and testing

**CONFORMANCE WITH STANDARD SECTIONS\***

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 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		

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11607 packaging for terminally sterilized medical devices - Part 1 & Part 2

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-193, 14-194

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

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Title of guidance: \_\_\_\_\_

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11607 packaging for terminally sterilized medical devices - Part 1 & Part 2

**CONFORMANCE WITH STANDARD SECTIONS\***

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 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		

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM D4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-300

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

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
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Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ASTM D4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems

**CONFORMANCE WITH STANDARD SECTIONS\***

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

TYPE OF DEVIATION OR OPTION SELECTED ♦  
Distribution Cycle 13

DESCRIPTION  
Air (intercity) and motor freight (local, single package up to 150 lb (61.8 kg).

JUSTIFICATION  
Met guidance requirement

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F 1980-07 Standard guide for accelerated aging of sterile barrier systems for medical devices

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-229

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F 1980-07 Standard guide for accelerated aging of sterile barrier systems for medical devices

**CONFORMANCE WITH STANDARD SECTIONS\***

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

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F88-00: 2009 Standard Test Method for Seal Strength of Flexible Barrier Materials.

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-283

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

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Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ASTM F88-00: 2009 Standard Test Method for Seal Strength of Flexible Barrier Materials.

**CONFORMANCE WITH STANDARD SECTIONS\***

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 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
----------------	---------------	---

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.*

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 <sup>1</sup>

ASTM F2096-04, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-123

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

<sup>4</sup> 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.

<sup>5</sup> 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>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ASTM F2096-04, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test).

**CONFORMANCE WITH STANDARD SECTIONS\***

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

DESCRIPTION

JUSTIFICATION

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <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

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <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

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♦ 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.

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Rockville, MD 20850

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**APPENDIX A: 510(k) SUMMARY**

**Sponsor/Submitter:** Acclarent, Inc.  
1525-B O'Brien Drive  
Menlo Park, California 94025

**Contact Person:** Keri Yen  
Regulatory Affairs Specialist  
Phone: (650) 687-5874  
Fax: (650) 687-4449

**Date of Submission:** July 3, 2007

**Device Trade Name:** *Relieva Luma*<sup>TM</sup> Sinus Illumination System

**Common Name:** Sinus Guidewire

**Device Classification:** Class I

**Regulation Number:** 21 CFR 878.4800

**Classification Name:** Manual surgical instrument for general use

**Product Code:** KAM

**Predicate Device:** *Relieva*<sup>TM</sup> Sinus Guidewire (K043445)

**Device Description:** The *Relieva Luma*<sup>TM</sup> Sinus Illumination System is a flexible device that transmits light at the distal tip. The system also contains two accessories: a light cable and an adapter.

**Indications for Use:** The *Relieva Luma*<sup>TM</sup> Sinus Illumination System is intended to provide means to access the sinus space for diagnostic and therapeutic procedures in conjunction with other nasal and sinus products. It is also intended to illuminate within and transilluminate across nasal and sinus structures.

**Technological Characteristics:** The *Relieva Luma*<sup>TM</sup> Sinus Illumination System is a device that allows for access to the desired sinus space. Light from the distal tip of the device can be seen via transillumination. The device is connected to any standard light source via a light cable and an adapter.

**Performance Data:** The *Relieva Luma*<sup>TM</sup> Sinus Illumination System met all performance testing acceptance criteria.

**Summary of Substantial Equivalence:** The *Relieva Luma*<sup>TM</sup> Sinus Illumination System is substantially equivalent to the predicate device as confirmed through relevant performance tests.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Acclarent, Inc.  
c/o Keri Yen  
Regulatory Affairs Specialist  
1525-B O'Brien Drive  
Menlo Park, CA 90425

SEP 28 2007

Re: K071845

Trade/Device Name: Relieva Luma™ Sinus Illumination System  
Regulation Number: 21 CFR 878.4800  
Regulation Name: Manual surgical instrument for general use  
Regulatory Class: Class I  
Product Code: KAM  
Dated: August 30, 2007  
Received: August 31, 2007

Dear Ms. Yen:

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.

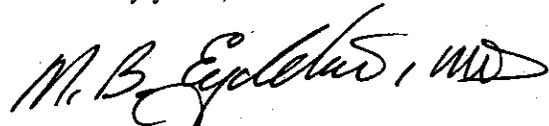
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear, Nose  
and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071845

Trade Name: *Relieva Luma*<sup>TM</sup> Sinus Illumination System

Common Name: Sinus Guidewire

Indications For Use: The *Relieva Luma*<sup>TM</sup> Sinus Illumination System is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures in conjunction with other nasal and sinus products. It is also intended to illuminate within and transilluminate across nasal and sinus structures.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

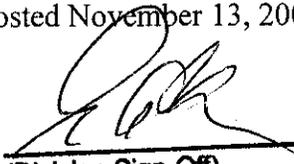
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)



(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number   K071845



**Instructions for Use**

*Relieva Luma*<sup>TM</sup>  
Sinus Illumination System

**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.**

**CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

**STERILITY:** The *Relieva Luma Sinus Illumination System* is sterilized with ethylene oxide gas.

**SINGLE USE:** The *Relieva Luma Sinus Illumination System* is intended for single patient use only. DO NOT resterilize and/or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

**STORAGE:** Store in a cool, dry place.

**DESCRIPTION**

The *Relieva Luma Sinus Illumination System* is a 0.035"-compatible flexible instrument that transmits light from the proximal to distal tip. The *Relieva Luma Sinus Illumination System* consists of a Light Guide Cable connector, the flexible instrument body, and a distal Light Lens (see figure 1). It is supplied with a pre-shaped or straight distal tip.

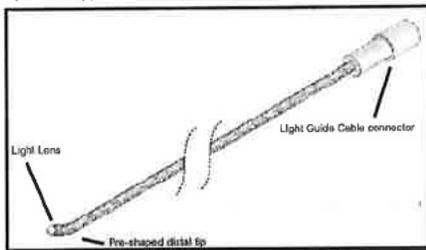


Figure 1.

**INDICATIONS FOR USE**

The *Relieva Luma Sinus Illumination System* is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures in conjunction with other nasal and sinus products. It is also intended to illuminate within and transilluminate across nasal and sinus structures.

**CONTRAINDICATIONS:**

None.

**WARNINGS**

- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Never advance or retract the *Relieva Luma Sinus Illumination System* against unknown resistance as this can cause tissue trauma or device damage.
- Only physicians trained in the use of *Balloon Sinuplasty™* technology should use this instrument.

**PRECAUTIONS**

- The *Relieva Luma Sinus Illumination System* is a precision optical instrument and must be handled with care. Do not pinch or kink the *Relieva Luma Sinus Illumination System* body.
- If supplied with a pre-shaped tip, do not attempt to alter the distal tip of the *Relieva Luma Sinus Illumination System*, as this may result in device damage.
- If using the *Relieva Luma Sinus Illumination System* to trans-illuminate the frontal sinus, pre-operative review of a CT, x-ray or other image is recommended to help facilitate identification of the frontal sinus.

**COMPATIBILITY**

The *Relieva Luma Sinus Illumination System* is compatible with all *Balloon Sinuplasty™* instruments that use 0.035" Sinus Guidewires. It is compatible with the custom *Relieva Luma Light Guide Cable*, and Xenon light sources. Please refer to the appropriate Instructions for Use when using with compatible devices.

**INSTRUCTIONS FOR USE**

1. Remove the *Relieva Luma Sinus Illumination System* from the protective packaging.
2. Ensure that the distal Light Lens and proximal Light Guide Cable connector surface are clean. A soft wetted towel may be used to clean the surfaces if necessary.
3. Connect a *Relieva Luma Light Guide Cable* to the Light Guide Cable connector on the proximal end of the *Relieva Luma Sinus Illumination System*.

**NOTE:** Use only the *Relieva Luma Light Guide Cable* with the *Relieva Luma Sinus Illumination System*, as standard light guide cables may damage the optical components.

4. Activate the light source. Confirm that light is visible at the distal end of the *Relieva Luma Sinus Illumination System*.

*If using with a Relieva® family Sinus Balloon Catheter:*

1. Starting at the distal end of the *Relieva Luma Sinus Illumination System*, load the proximal end of the *Relieva Sinus Balloon Catheter* onto the *Relieva Luma Sinus Illumination System*. This must be performed prior to insertion into the nasal cavity.

*If using to transcutaneously illuminate through sinus structures:*

1. Advance the instrument into the target sinus until some light resistance is felt.

**NOTE:** Light from the tip of the *Relieva Luma Sinus Illumination System* may transcutaneously illuminate tissue structures. The location and intensity of the transcutaneous illumination will depend on the sinus entered, orientation of the *Sinus Illumination System*, and patient characteristics.

2. To enhance the intensity of the transcutaneous illumination provided by the *Relieva Luma Sinus Illumination System* it may be necessary to reduce the number of competing light sources (i.e. endoscope or room lights) or to reposition the location of the instrument tip.
3. Confirm placement and position of the *Relieva Luma Sinus Illumination System* with endoscopic, fluoroscopic and/or transcutaneous illumination visualization.

**NOTE:** Rinse the *Relieva Luma Sinus Illumination System* distal tip in saline after use in each sinus to ensure maximum light transmission for subsequent uses in the same patient.



**GRAPHIC SYMBOLS CONTAINED  
ON DEVICE LABELING**

	Batch Code		On Order of Physician Only
	Sterilized with ethylene oxide		Date of Manufacture
	Use by		Consult Instructions For Use
	Do not re-use		Device compatibility
	Length		Tip Shape
	Keep dry		Maximum temperature
	Keep Away from Sunlight		CE Mark
	European Authorized Representative		Manufactured By

**Product Information Disclosure**

Acclarent, Inc. has exercised reasonable care in the manufacture of this device. Acclarent, Inc. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Acclarent, Inc.'s control, directly affect this device and the results obtained from its use. Acclarent, Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Acclarent, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

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U.S. Patent Nos. 7,500,971 and 7,462,174 and other U.S. and foreign patents pending.

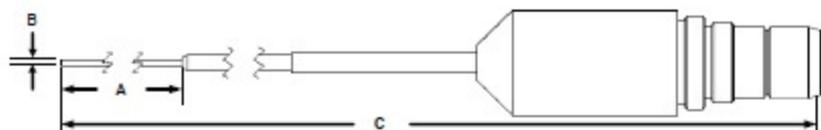


# PathAssist™

## LIGHT FIBER

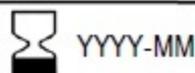
REF LF-100

<b>A</b>	Length 27.6cm NOMINAL	<b>B</b>	Diameter .020"	<b>C</b>	Overall Length 117cm
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MODEL PLF

LOT XXXXX



YYYY-MM

STERILE EO

Does Not Contain  
Natural Rubber LatexDo Not Use if Package  
is Damaged

Rx ONLY

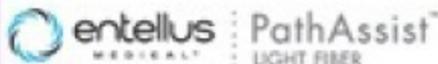
Single Use

Consult Instructions for Use  
<http://www.LightFiber-IFU.com>

6705 Wedgwood Court N  
Maple Grove, MN 55311  
[www.entellusmedical.com](http://www.entellusmedical.com)  
866-620-7615 fax 888-620-7616  
Email: [customerservice@entellusmedical.com](mailto:customerservice@entellusmedical.com)

Package Contents:  
(1) Light Fiber  
(1) Male Tudy Borst

1961-001-r02



REF LF-100

LOT XXXXX



YYYY-MM



# PathAssist™

## LIGHT FIBER

REF LF-100

<b>A</b> Length 27.6cm NOMINAL	<b>B</b> Diameter .020"	<b>C</b> Overall Length 117cm
--------------------------------------	----------------------------	----------------------------------



MODEL PLF

LOT XXXXX

YYYY-MM

STERILE EO

Does Not Contain  
Natural Rubber Latex

Do Not Use if Package  
is Damaged

Rx ONLY

Single Use



Consult Instructions for Use  
<http://www.LightFiber-LFU.com>

Package Contents:  
(1) Light Fiber  
(1) Male Tucky Borst



6705 Wedgwood Court N  
Maple Grove, MN 55311  
[www.entellusmedical.com](http://www.entellusmedical.com)  
866-620-7615 fax 888-620-7616  
Email: [customerservice@entellusmedical.com](mailto:customerservice@entellusmedical.com)

Path Assist Light Fiber

REF LF-100 LOT XXXXX

Path Assist Light Fiber

REF LF-100 LOT XXXXX

## INSTRUCTIONS FOR USE

### PathAssist™ Light Fiber

*Read all Instructions prior to use*

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

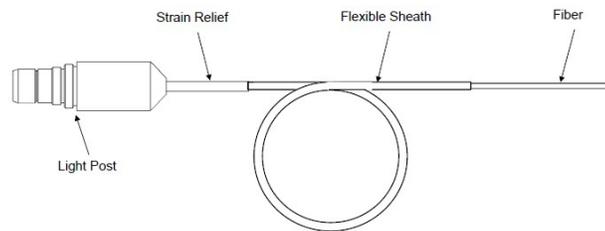
**Sterility:** Provided Sterile, Ethylene Oxide (EO) Sterilization

**Single Use:** Disposable, For Single Patient Use Only, Do Not Resterilize and/or Reuse

**Storage:** Store in a cool, dry place

#### **Description**

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a fiber nominal working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm.



The Light Fiber is packaged with a commercially available male tuohy borst adapter.

#### **Indication For Use**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

#### **Contraindications**

None known

#### **Warnings**

- Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.
- Single use only. Do not re-sterilize or re-use, as it may result in compromised device performance and risk improper sterilization and cross contamination.
- Never advance or withdraw the device against unknown resistances as this can cause tissue trauma or device damage.
- Do not use the device with a Xenon light source > 300W and a light cable < 2.5mm or > 3.5mm. High energy light radiated through devices can result in high temperatures in front of the light outlet and at the connection point to the light cable, including the light post adapters. Use of a higher wattage light source may result in burns or permanent tissue damage to the user or the patient.
- Do not rest the device on the patient during surgery while it is connected to a light source, as this could result in burns to the patient.
- Allow the device to cool for a few minutes before disassembling from the light cable and light post adapter.

#### **Precautions**

- Due to the variability of sinus anatomy, review radiographic imaging (CT scan) prior to the procedure
- Do not kink the Light Fiber as this may damage the device.
- If using Light Fiber with the XprESS device, be sure to pre-load the Light Fiber into XprESS prior to shaping it into a maxillary bend configuration (i.e., approximately 135° bend) as the Light Fiber will not load when XprESS is pre-shaped in a maxillary configuration.

- Do not use the device for external transillumination of maxillary sinus by applying the device to the hard palate, as this use has not been tested.

### **Adverse Effects**

Possible adverse effects include, but are not limited to, the following:

- Cerebrospinal fluid leak
- Damage of the orbital wall or other structures of the eye
- Tissue inflammation or trauma

### **Compatibility**

- The device is compatible with working lumen instruments with an OD  $\geq$  2mm (malleable suctions, sinus cannulas), and with an internal lumen diameter  $\geq$  0.035" and a length  $\leq$  27.5cm. Examples of devices that meet these requirements include XprESS™ Multi-Sinus Dilation Tool and Medtronic MCSK5 Suction Tube.
- The device is compatible with 2.5mm and 3.5mm light cables and standard light post adapters (ACMI, RICHARD WOLF, KARL STORZ ), and a 300W Xenon light source.

### **Instructions for Use**

1. Remove the Light Fiber and tuohy from the protective packaging.
2. Attach the tuohy to the working lumen instrument.
3. Load the distal end of the Light Fiber into the working lumen instrument aligning the distal tip of the fiber with the distal end of the instrument.
4. Secure the Light Fiber in place by tightening the tuohy.
5. Shape loaded working lumen instrument (if applicable) to desired bend configuration for targeted sinus.
6. Connect a 2.5mm or 3.5mm light cable and light post adapter (if necessary) to the light post of the Light Fiber. Connect the light cable to a 300W Xenon light source.
7. Activate the light source. Confirm that light is being transmitted through the Light Fiber.
  - The light intensity transmitted through the Light Fiber can be increased by adjusting the output of the light source or by using a smaller diameter light cable.
8. Under endoscopic visualization, place the working lumen instrument into the target location to illuminate within and transilluminate across nasal and sinus structures. Some tissue removal may be necessary to access the target location.
  - Projected illumination can be enhanced by reducing the number of competing light sources (i.e. endoscope or room light) or by advancing tip of the Light Fiber distal from the working lumen instrument.
9. After procedure, dispose of device according to appropriate environmental health safety guidelines.

### **Limited Warranty**

Entellus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this device. Entellus Medical excludes all other warranties, whether expressed or implied, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness since handling and storage as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical's control, directly affect the device and the results obtained from its use. Entellus Medical shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Entellus Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Refer to *Entellus Medical, Inc. Standard Terms and Conditions*.

Graphic Symbols Contained on Device labeling

 Consult Instructions for use	<b>LOT</b> Lot Number	<b>MODEL</b> Model Number	 Use By	<b>REF</b> Reorder Number
<b>STERILE</b> <b>EO</b> Sterilization with Ethylene Oxide Gas	 Manufacturer	 Do Not Reuse	<b>Rx Only</b> Prescription Use Only	

PathAssist and XprESS are trademarks of Entellus Medical.

ACMI is a trademark of Gyrus ACMI, Inc. of Southborough, MA.

RICHARD WOLF is a trademark of Richard Wolf GmbH of Knittlingen, Germany.

KARL STORZ is a trademark of Karl Storz GmbH of Tuttlingen, Germany.



Manufactured by:

**Entellus Medical Inc.**

6705 Wedgwood Court North

Maple Grove, MN 55311

(763) 463-1595

[www.entellusmedical.com](http://www.entellusmedical.com)







































































































































































































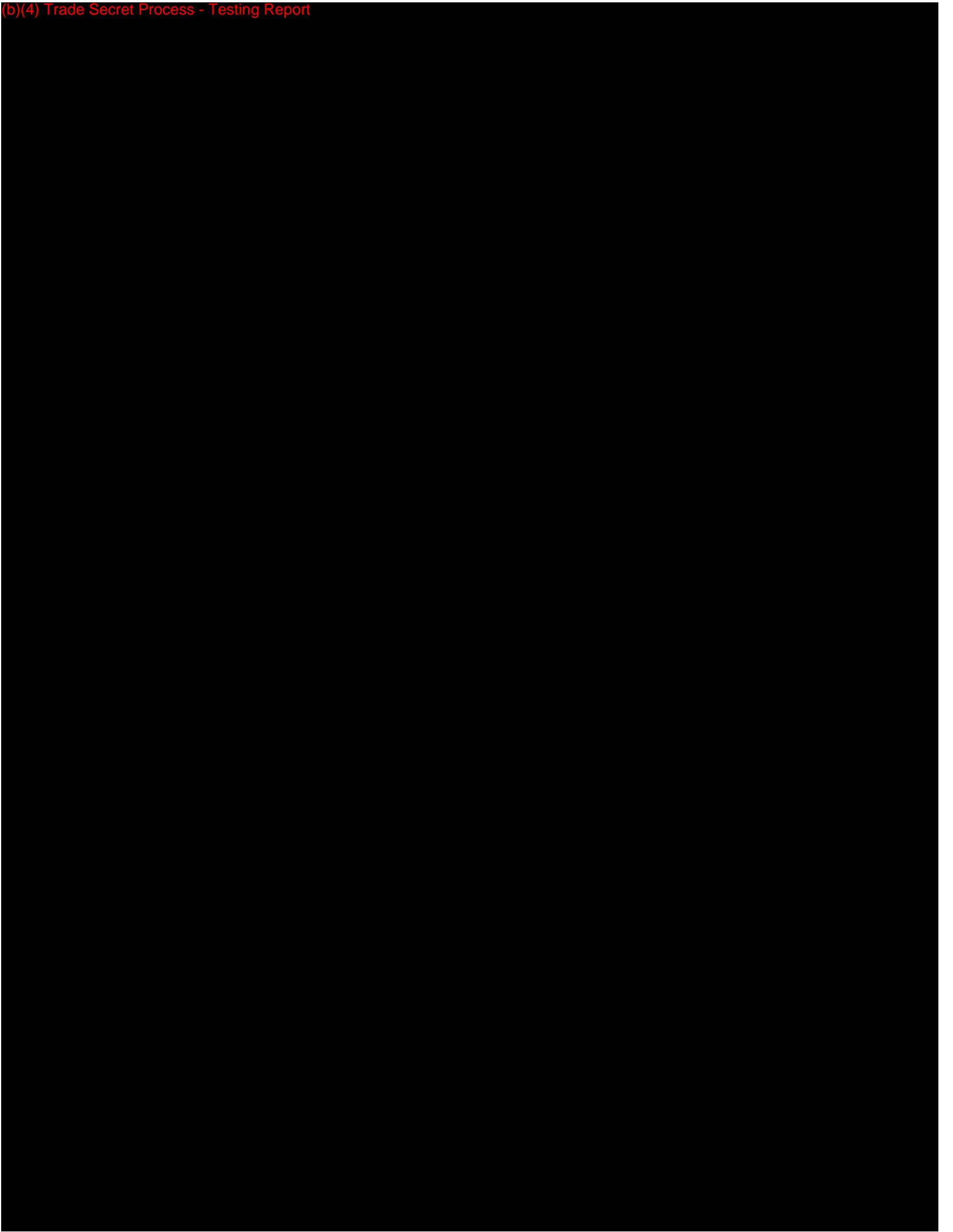
















































































































































































































































































































































**COVER SHEET MEMORANDUM**

**From:** Reviewer Name Andrew Yang  
**Subject:** 510(k) Number K111763/S001  
**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%207%202%2007.doc](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	<i>Attach IFU</i>	X	
<u>510(k) Summary</u> , /510(k) Statement	<i>Attach Summary</i>	X	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		X X	
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			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, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ?			X X
(If not, then applicant must be contacted to obtain completed form.)			
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 Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, <a href="http://www.fda.gov/cdrh/osb/guidance/316.html">http://www.fda.gov/cdrh/osb/guidance/316.html</a> )	Contact OSB.	X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC.	X

**Regulation Number**

874.4420

**Class\***

1

(\*If unclassified, see 510(k) Staff)

**Product Code**

LRC

**Additional Product Codes:**

Review:

*[Signature]*  
(Branch Chief)

ENTIS  
(Branch Code)

9/15/2011  
(Date)

Final Review:

*[Signature]*  
(Division Director)

9/15/11  
(Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification 510(k) Review
Traditional
K111289/S001

Date: September 6, 2011
To: The Record
From: Andrew Yang

Office: ODE
Division: DONED

510(k) Holder: Entellus Medical, Inc.
Device Name: PathAssist Light Fiber
Contact: Karen E. Peterson, Vice President Clinical, Regulatory and Quality
Phone: 763-463-7066
Mobile: 651-398-4341
Fax: 763-463-1599
Email: kpeterson@entellusmedical.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce PathAssist Light Fiber 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, and 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?, and Is the device sterile?

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a nominal fiber working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm. See photo below.

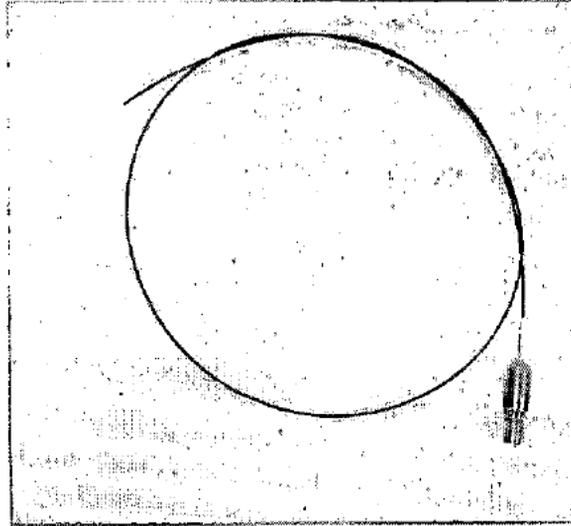
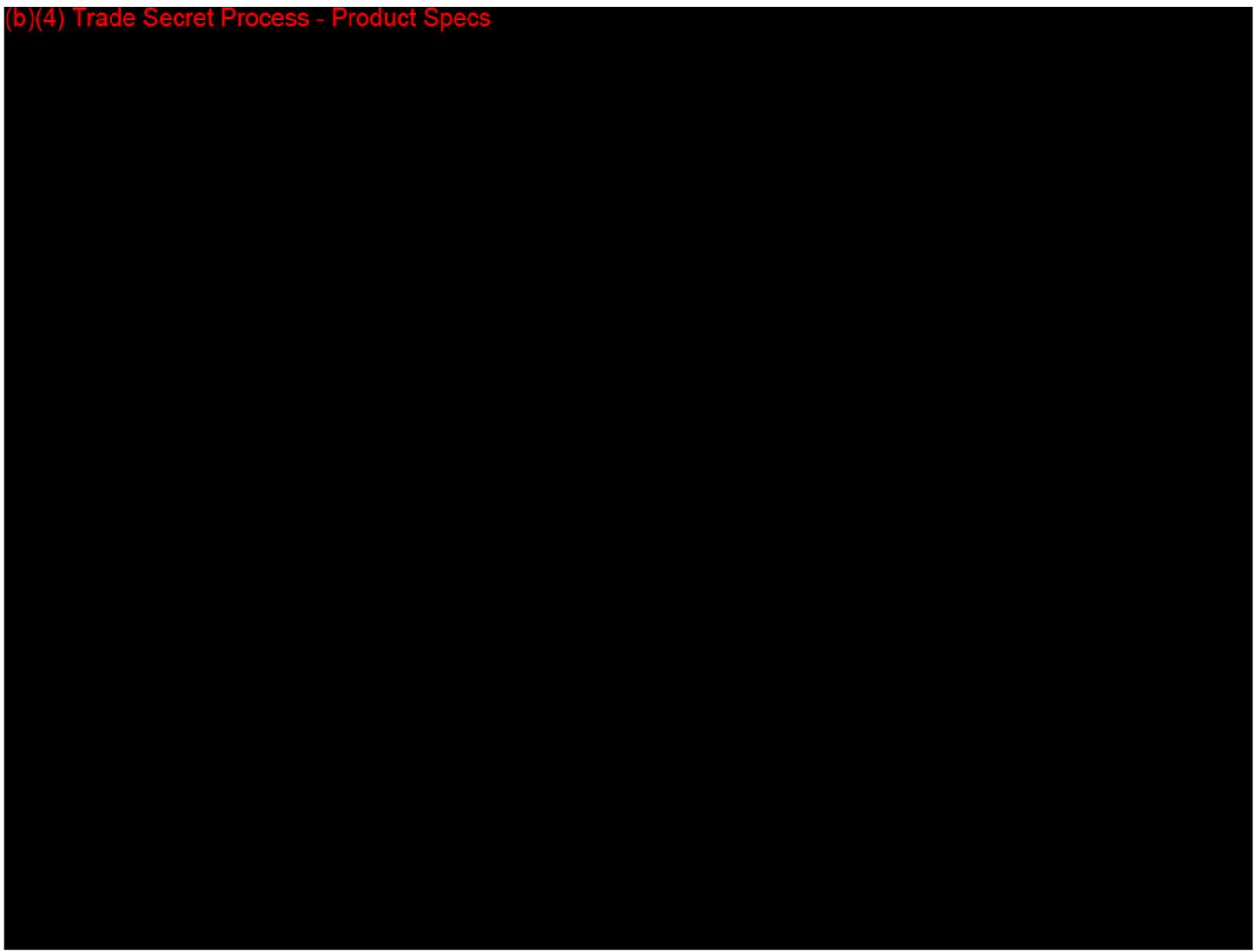


Figure 13-1 PathAssist Light Fiber

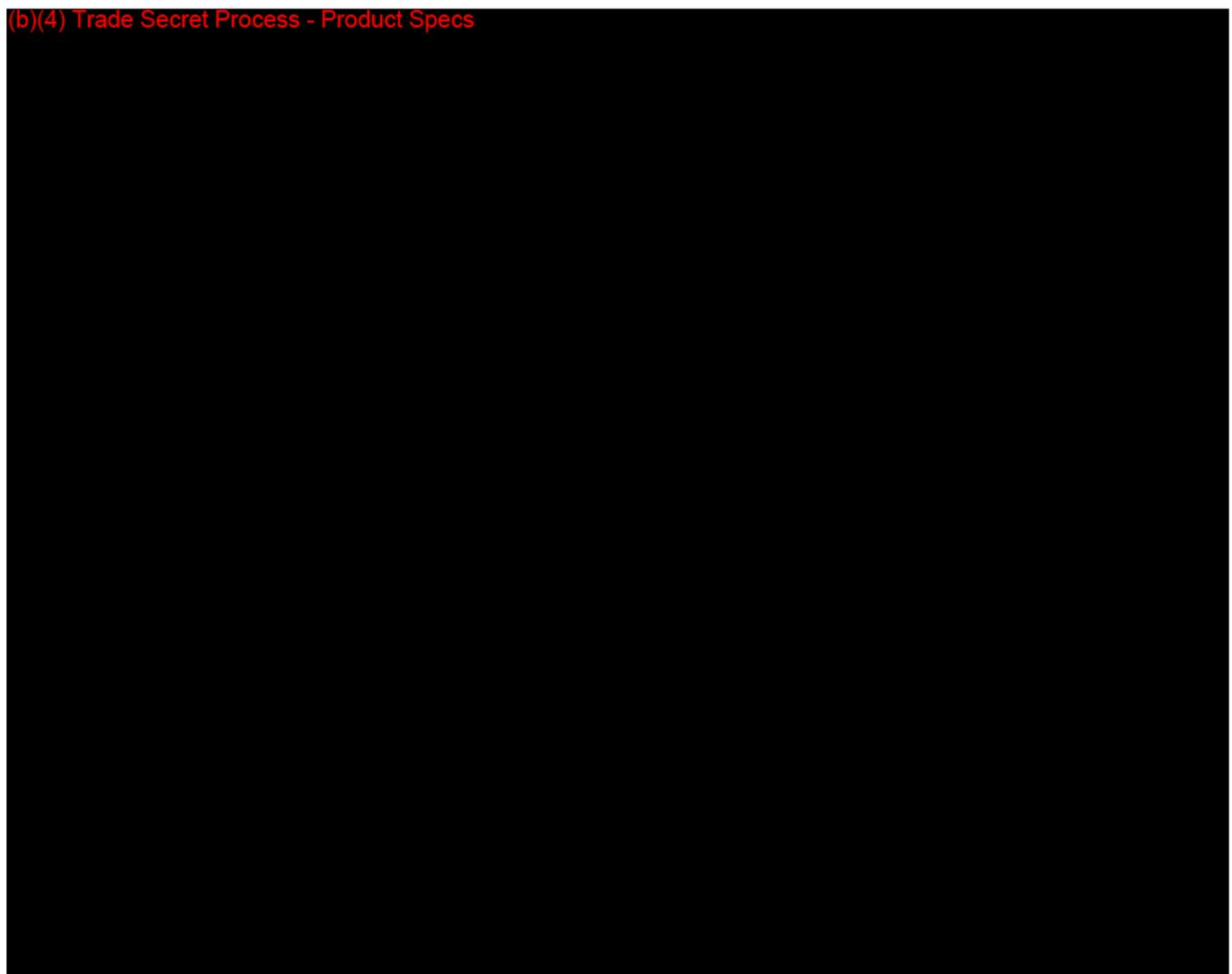
**IV. Indications for Use**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

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



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



VI. Labeling

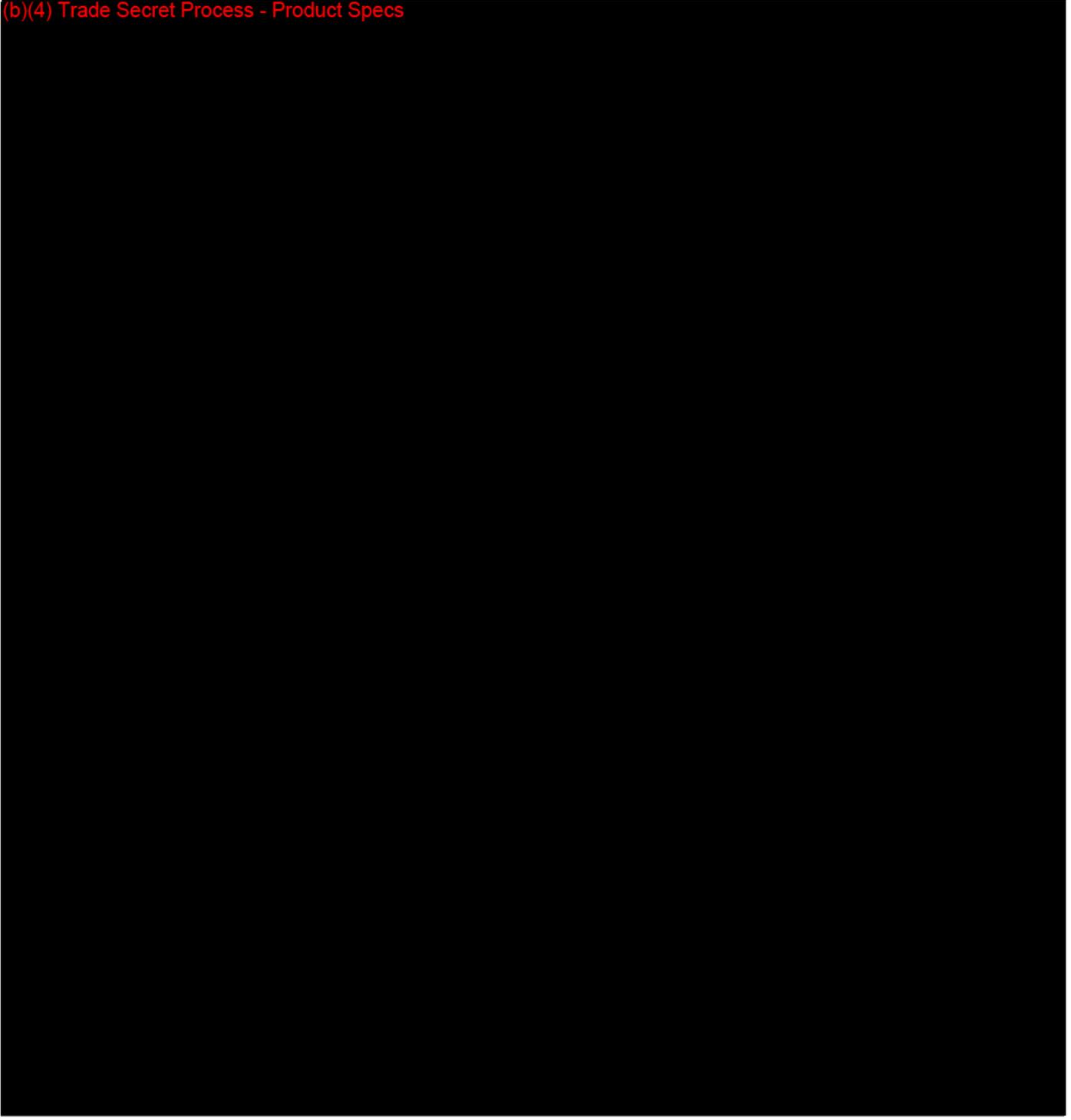
15. Proposed Labeling

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

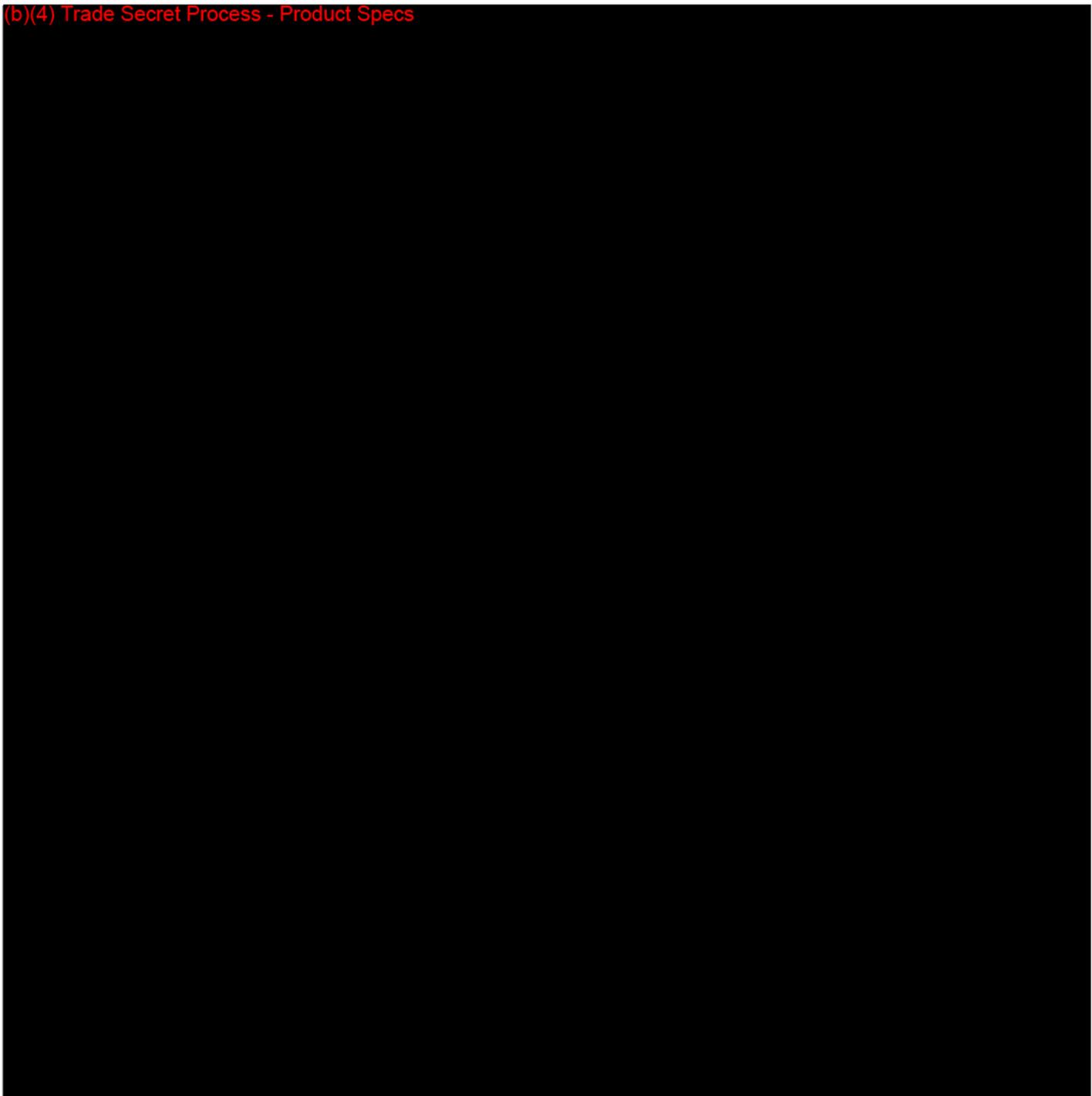


VII. Sterilization/Shelf Life/Reuse

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

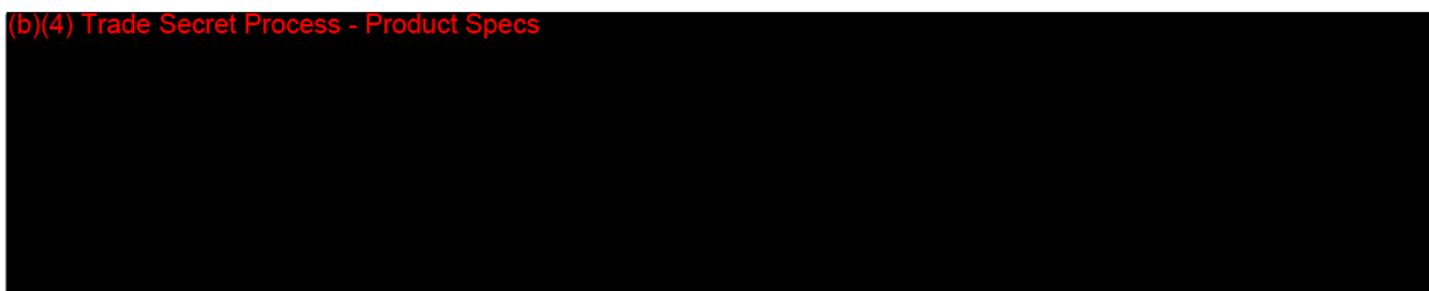


(b)(4) Trade Secret Process - Product Specs

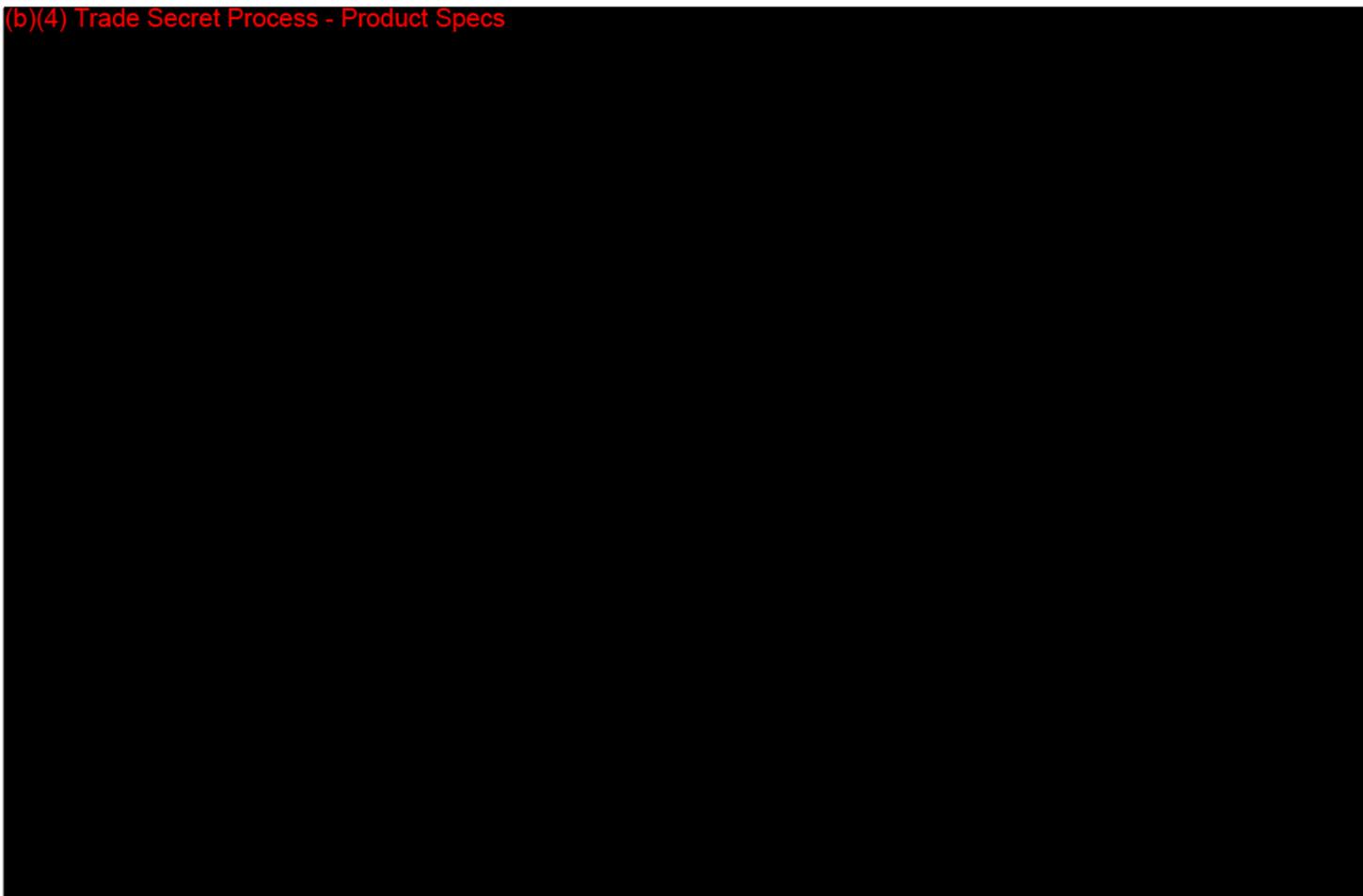


VIII. Biocompatibility

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



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



IX. Software

n/a

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

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

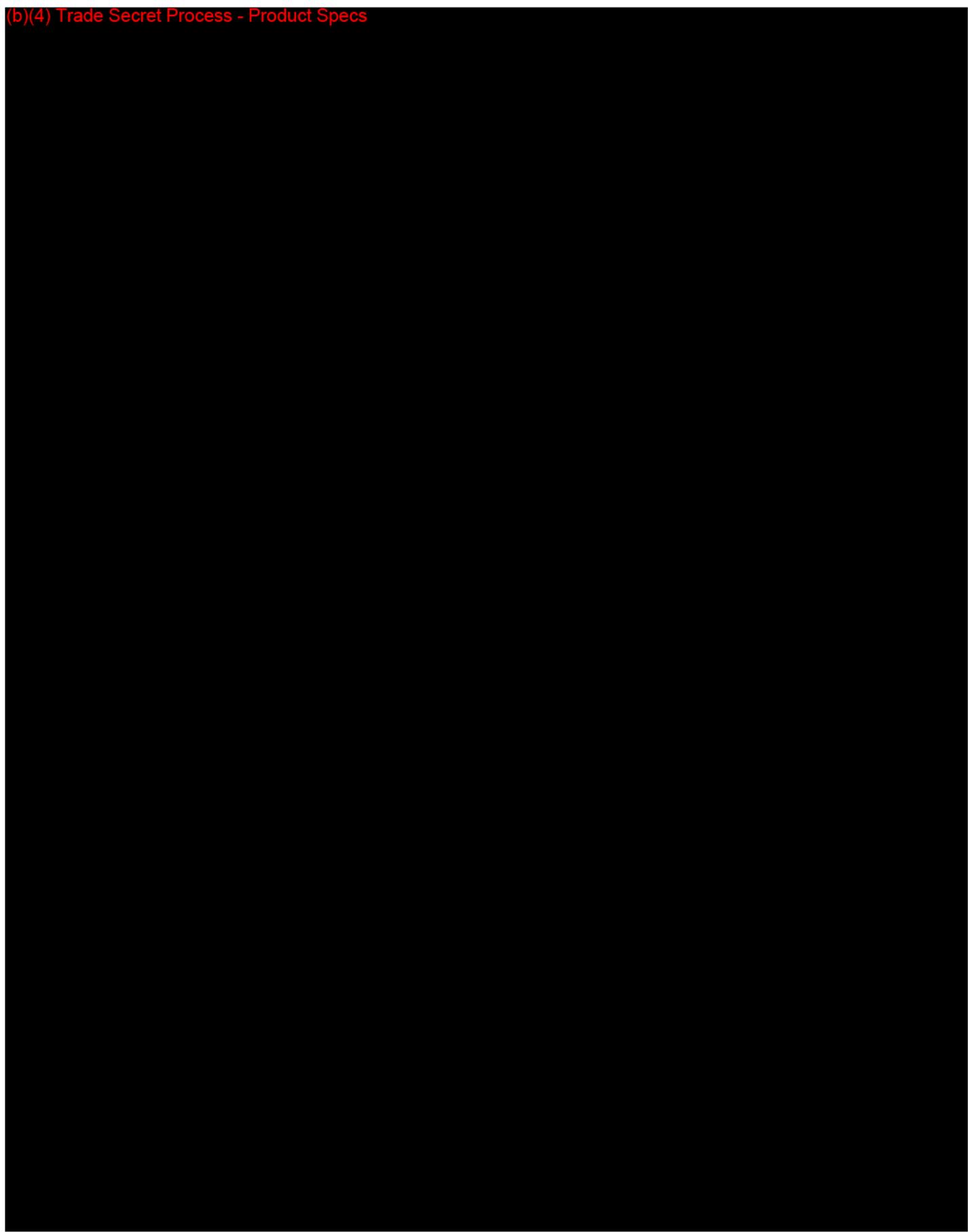


XI. Performance Testing – Bench

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



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



**XII. Performance Testing – Animal**

n/a

**XIII. Performance Testing – Clinical**

n/a

**XIV. 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?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See

[http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

*n/a*

2. Explain why there is or is not a new effect or safety or effectiveness issue:

*n/a*

3. Describe the new technological characteristics:

*n/a*

4. Explain how new characteristics could or could not affect safety or effectiveness:

*n/a*

5. Explain how descriptive characteristics are not precise enough:

*n/a*

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

*n/a*

7. Explain why existing scientific methods can not be used:

*n/a*

8. Explain what performance data is needed:

*n/a*

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

n/a

**XV. Deficiencies**

n/a

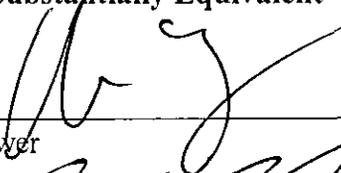
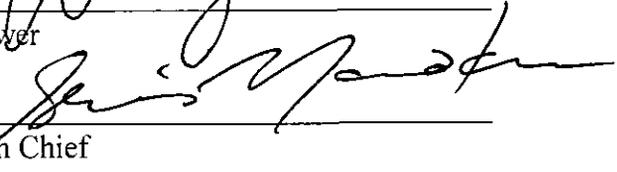
**XVI. Advisory**

n/a

**XVII. Recommendation**

Regulation Number: 21 CFR 874.4420  
Regulation Name: ENT manual surgical instrument  
Regulatory Class: Class I  
Product Code: LRC

**SE – Substantially Equivalent**

  
\_\_\_\_\_  
Reviewer  
  
\_\_\_\_\_  
Branch Chief

9/6/11  
\_\_\_\_\_  
Date  
9/15/11  
\_\_\_\_\_  
Date



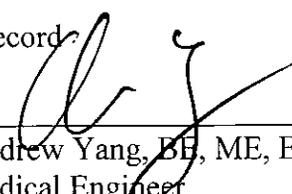
**Memorandum**

**Mechanical Engineering / Electromagnetic Compatibility & Electrical Safety**

Date: September 1, 2011

To: The Record

From:

  
LT Andrew Yang, BE, ME, EIT  
Biomedical Engineer  
Ear Nose and Throat device Branch (ENTB)  
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices

Subject: K111763/S001

Device: Entellus Medical's PathAssist Light Fiber

Recommendation: **SE – Substantially Equivalent**

**INDICATIONS FOR USE (IFU)**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

**DEVICE DESCRIPTION**

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a nominal fiber working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm. See photo below.

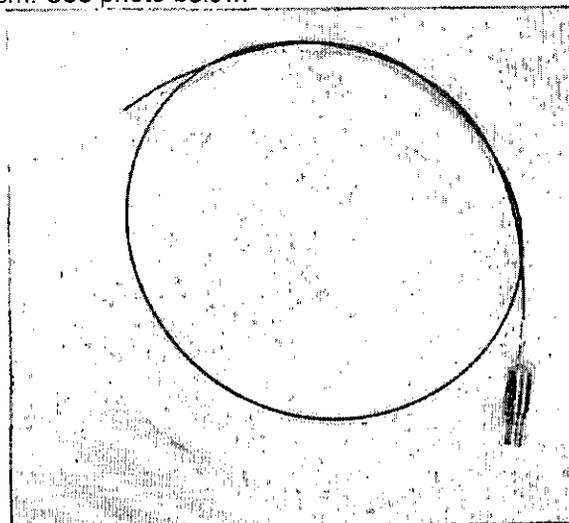


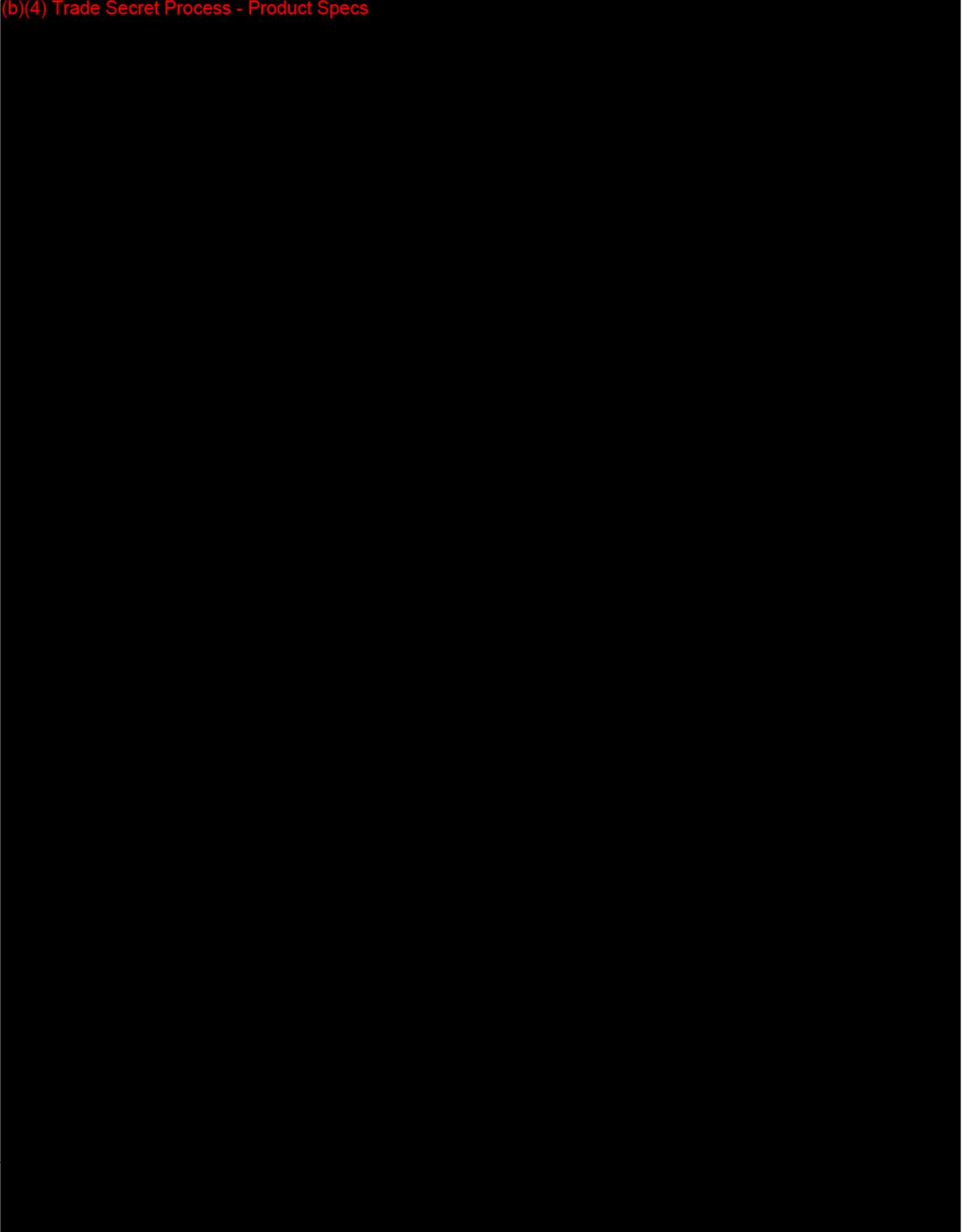
Figure 13-1 PathAssist Light Fiber

Note:

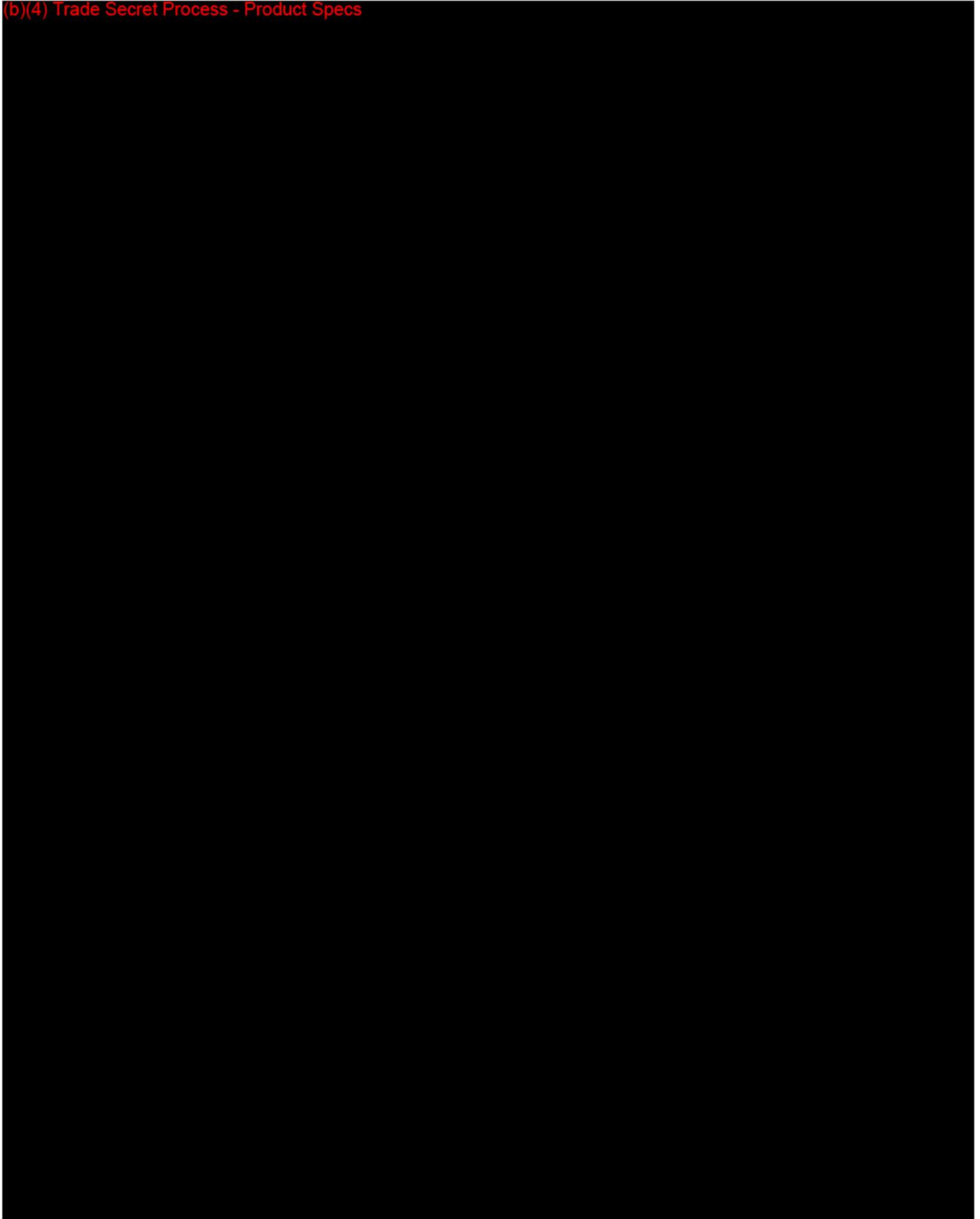
Arial font indicates sponsor language

Times New Roman font indicates reviewer language

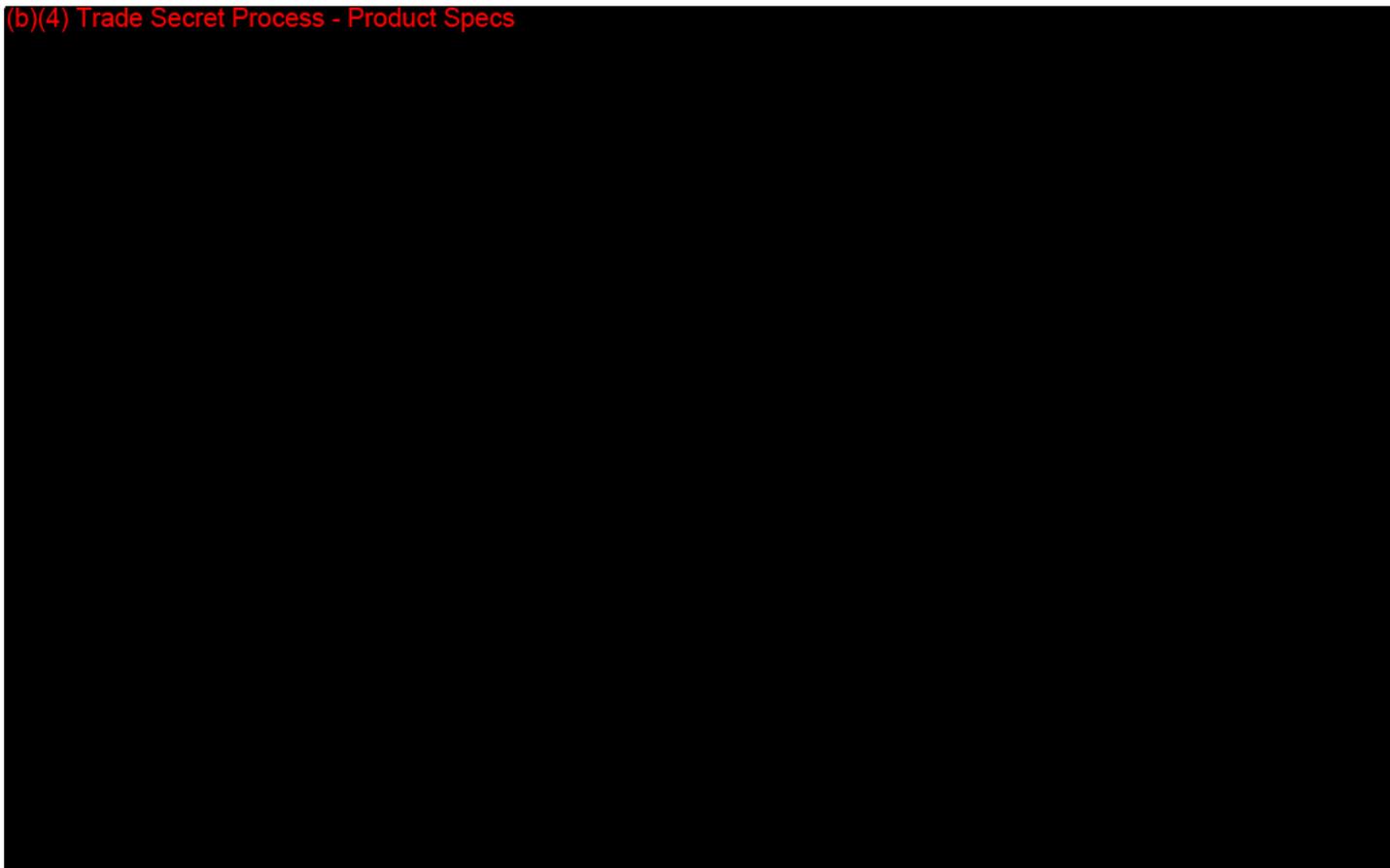
(b)(4) Trade Secret Process - Product Specs



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



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



**SE – Substantially Equivalent**

Path Assist light Fiber  
K111763/S001  
Entellus

**OFFICE OF DEVICE EVALUATION**  
**510 (k) Clinical Review of Responses**  
**K111763/S001**

**From:** Anjum Khan, M.D., MPH  
Medical Officer, ENTB/DONED/ODE

**To:** Andrew Yang,  
Biomedical Engineer, ENTB/DONED/ODE

**Cc:** Sirinivas Nandkumar, Ph.D  
Branch Chief, ENTB/DONED/ODE

**Cc:** Eric Mann, M.D., PhD  
Clinical Deputy Director, Division of Ophthalmic/ENT  
ODE/DONED

**Date:** 09-02-11

**Subject:** Path Assist Light Fiber-Response to request for Additional  
Information

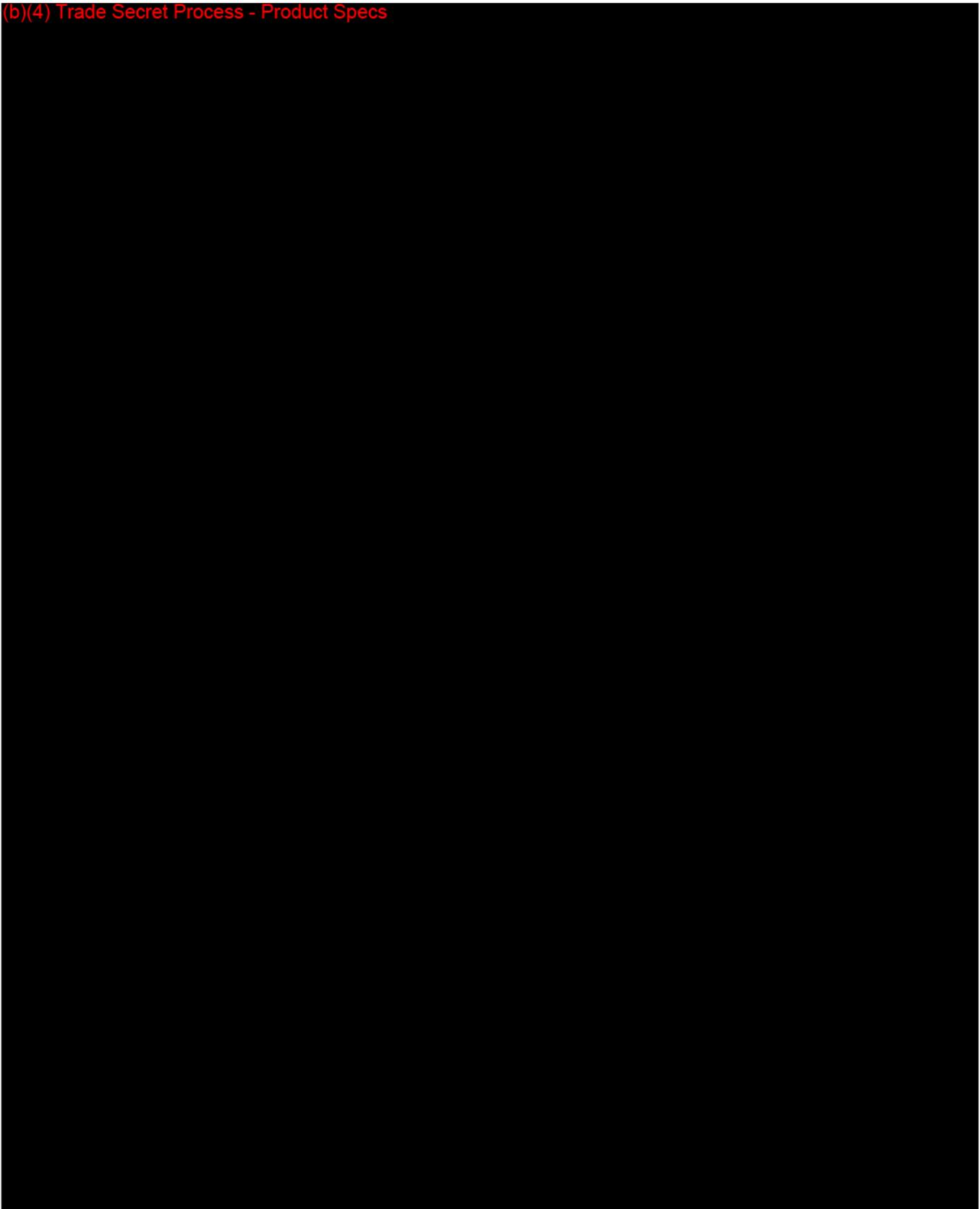
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(b)(4) Trade Secret Process - Product Specs



Path Assist light Fiber  
K111763/S001  
Entellus

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

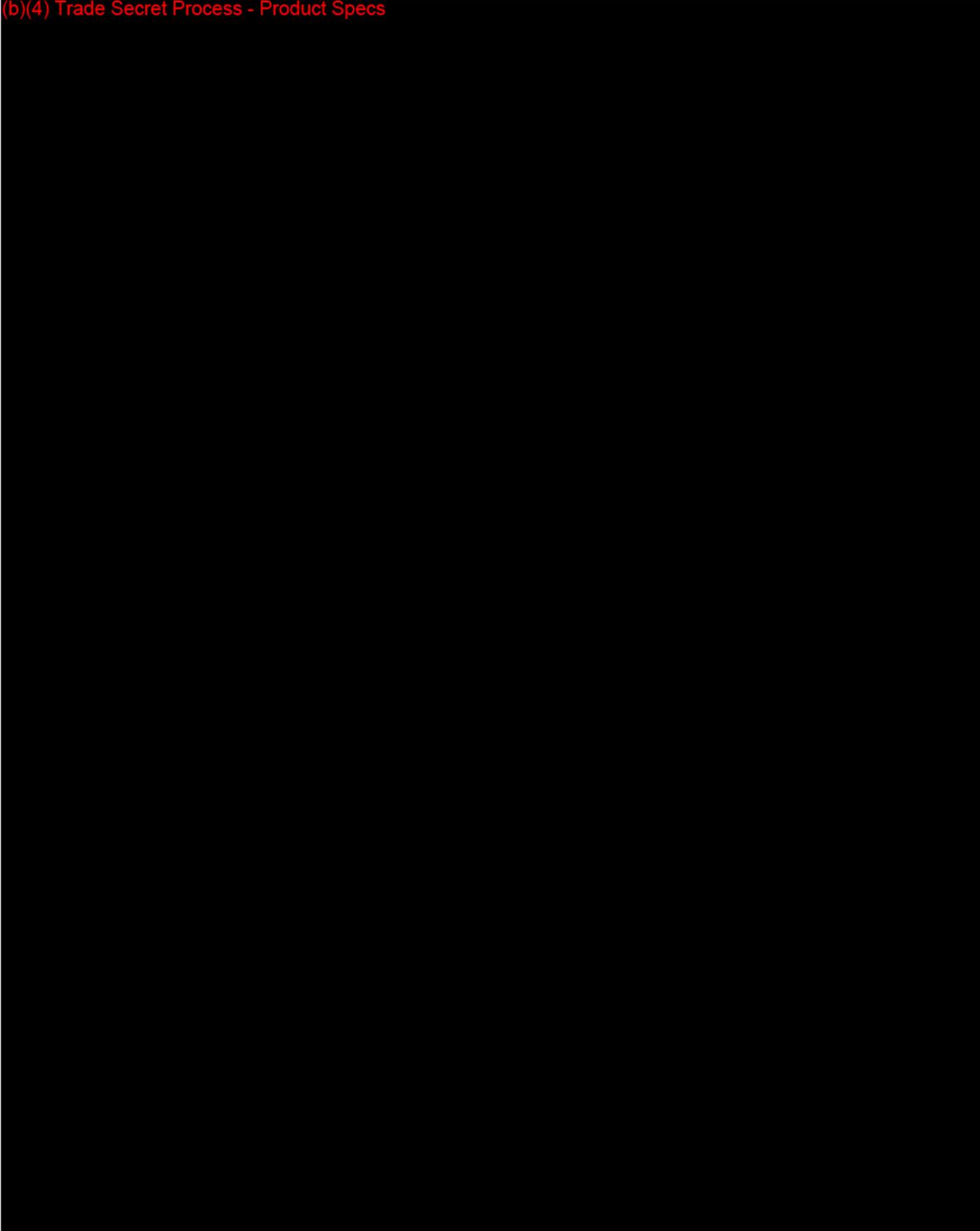


Path Assist light Fiber

K111763/S001

Entellus

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



**Benjamin, Mark D\***

---

**From:** Microsoft Exchange  
**To:** 'kpeterson@entellusmedical.com'  
**Date:** Monday, August 15, 2011 9:55 AM  
**Subject:** Relayed: Additional Information

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'kpeterson@entellusmedical.com'

Subject: Additional Information

---

Sent by Microsoft Exchange Server 2007

**Benjamin, Mark D\***

---

**From:** Benjamin, Mark D\*  
**Sent:** Monday, August 15, 2011 9:55 AM  
**To:** 'kpeterson@entellusmedical.com'  
**Subject:** Additional Information  
**Attachments:** image002.png

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service**

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center, WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20910-0002

August 15, 2011

PETERSON

E

KAREN

ENTELLUS MEDICAL, INC.  
 6705 WEDGWOOD COURT NORTH  
 MAPLE GROVE, MINNESOTA 55311  
 ATTN: KAREN E. PETERSON

510k Number: K111763

Product: PATHASSIST LIGHT FIBER

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.

8/15/2011

26

Sincerely,  
510(k) Staff

**Benjamin, Mark D\***

---

**From:** Microsoft Exchange  
**To:** 'kpeterson@entellusmedical.com'  
**nt:** Thursday, August 11, 2011 1:55 PM  
**Subject:** Relayed: Hold Letter

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'kpeterson@entellusmedical.com'

Subject: Hold Letter

---

Sent by Microsoft Exchange Server 2007

**Benjamin, Mark D\***

**From:** Benjamin, Mark D\*  
**Sent:** Thursday, August 11, 2011 1:55 PM  
**To:** 'kpeterson@entellusmedical.com'  
**Subject:** Hold Letter  
**Attachments:** image002.png

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service**  
 U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center, WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20904-0002

August 11, 2011

PETERSON  
E

KAREN  
 ENTELLUS MEDICAL, INC.  
 6705 WEDGWOOD COURT NORTH  
 MAPLE GROVE, MINNESOTA 55311  
 ATTN: KAREN E. PETERSON

510k Number: K111763

Product: PATHASSIST LIGHT FIBER

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.

8/11/2011

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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

32

**Yang, Andrew**

---

**From:** Karen Peterson [kpeterson@entellusmedical.com]  
**ent:** Wednesday, August 10, 2011 5:11 PM  
**To:** Yang, Andrew  
**Subject:** RE: K111763 Entellus Medical PathAssist Light Fiber

Much better  
Thanks much!

Karen Peterson  
VP Clinical, Regulatory & Quality  
Entellus Medical Inc.  
Office: 763-463-7066  
Cell: 651-398-4341  
Email: kpeterson@entellusmedical.com  
Corporate website: [www.entellusmedical.com](http://www.entellusmedical.com)  
Patient website: [www.sinussurgeryoptions.com](http://www.sinussurgeryoptions.com)

---

**From:** Yang, Andrew [mailto:Andrew.Yang@fda.hhs.gov]  
**Sent:** Wednesday, August 10, 2011 4:05 PM  
**To:** Karen Peterson  
**Subject:** RE: K111763 Entellus Medical PathAssist Light Fiber

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



LT Andrew Yang, BE, ME, EIT  
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
301-796-6860

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8/10/2011

33

---

**From:** Karen Peterson [mailto:kpeterson@entellusmedical.com]  
**Sent:** Wednesday, August 10, 2011 4:39 PM  
**To:** Yang, Andrew  
**Subject:** RE: K111763 Entellus Medical PathAssist Light Fiber

Hi Andrew,

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

Thanks,  
Karen

Karen Peterson  
VP Clinical, Regulatory & Quality  
Entellus Medical Inc.  
Office: 763-463-7066  
Cell: 651-398-4341  
Email: kpeterson@entellusmedical.com  
Corporate website: [www.entellusmedical.com](http://www.entellusmedical.com)  
Patient website: [www.sinussurgeryoptions.com](http://www.sinussurgeryoptions.com)

---

**From:** Yang, Andrew [mailto:Andrew.Yang@fda.hhs.gov]  
**Sent:** Wednesday, August 10, 2011 3:14 PM  
**To:** Karen Peterson  
**Subject:** K111763 Entellus Medical PathAssist Light Fiber

Dear Ms. Peterson:

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

LT Andrew Yang, BE, ME, EIT  
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
301-796-6860

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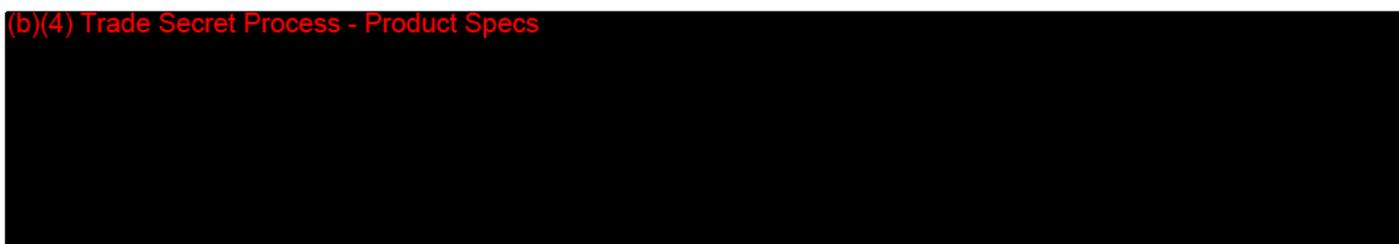
**Yang, Andrew**

---

**From:** Yang, Andrew  
**ent:** Wednesday, August 10, 2011 4:14 PM  
**To:** 'kpeterson@entellusmedical.com'  
**Subject:** K111763 Entellus Medical PathAssist Light Fiber  
**Attachments:** K111763 attachment.pdf

Dear Ms. Peterson:

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



LT Andrew Yang, BE, ME, EIT  
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
301-796-6860

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8/10/2011

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**COVER SHEET MEMORANDUM**

**From:** Reviewer Name Andrew Yang  
**Subject:** 510(k) Number K111763  
**To:** The Record

Please list CTS decision code TH

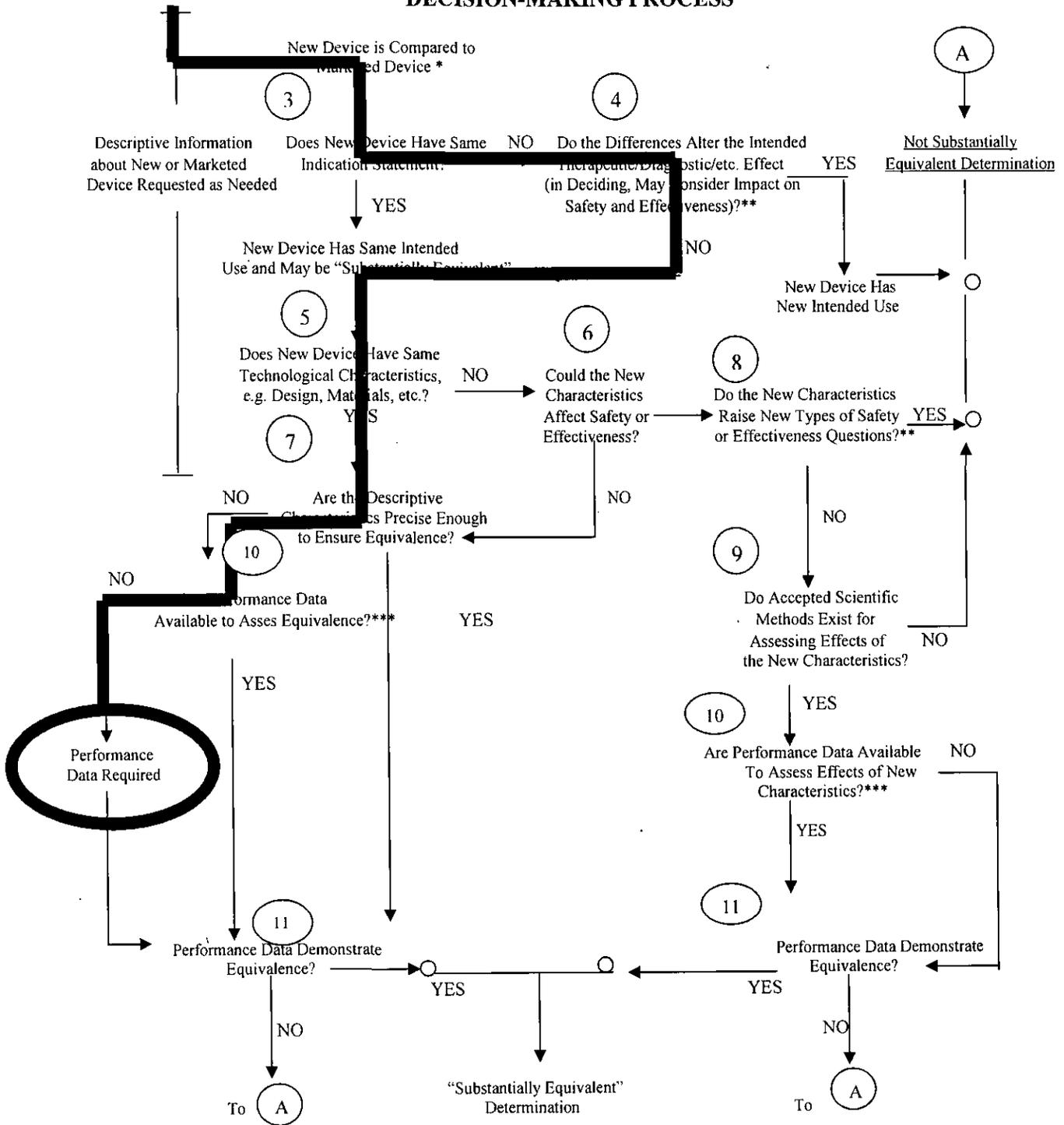
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- 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	<i>Attach IFU</i>	X	
<u>510(k) Summary</u> /510(k) Statement	<i>Attach Summary</i>	X	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	X	
Is the device Class III? If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		X
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		X X	
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			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 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	

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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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

## PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

<b>If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):</b>	<b>YES</b>	<b>NO</b>
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see <a href="H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC">H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC</a> )		X
2. Is the device exempt from 510(k) by regulation (Please see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC</a> or subject to enforcement discretion (No regulation - See 510(k) Staff)?)		X
3. Does this device type require a PMA by regulation? (Please see management.)		X
<b>Questions 4-8 are intended to help you start your review:</b>	<b>YES</b>	<b>NO</b>
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc</a> )		X
5. a. Did the firm request expedited review? (See management.)		X
b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , <a href="http://www.fda.gov/cdrh/mdufma/guidance/108.html">http://www.fda.gov/cdrh/mdufma/guidance/108.html</a> )		
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> <a href="http://www.fda.gov/cdrh/mdufma/guidance/1215.html">http://www.fda.gov/cdrh/mdufma/guidance/1215.html</a> )		X

## Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

**Guidance for Industry and FDA Staff  
Format for Traditional and Abbreviated 510(k)s**  
<http://www.fda.gov/cdrh/ode/guidance/1567.html>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">www.fda.gov/oc/mdufma/cover sheet.html</a>	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf</a>	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 <a href="http://www.fda.gov/cdrh/ode/guidance/1567.html">http://www.fda.gov/cdrh/ode/guidance/1567.html</a>	X		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_6">www.fda.gov/cdrh/devadvice/314312.html#link_6</a>	X		
<del>510(k) Summary</del> or 510(k) Statement	Device Advice "Content of a 510(k)" Section E <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_7">www.fda.gov/cdrh/devadvice/314312.html#link_7</a>	X		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_9">www.fda.gov/cdrh/devadvice/314312.html#link_9</a>	X		
Class III Summary and Certification	Class III Summary and Certification Form <a href="http://www.fda.gov/cdrh/manual/stmnciii.html">www.fda.gov/cdrh/manual/stmnciii.html</a>			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf</a> FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf</a> Financial Disclosure by Clinical Investigators <a href="http://www.fda.gov/oc/guidance/financialdis.html">www.fda.gov/oc/guidance/financialdis.html</a>			X
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations <a href="http://www.fda.gov/cdrh/ode/guidance/1131.html">www.fda.gov/cdrh/ode/guidance/1131.html</a> . FDA Standards program <a href="http://www.fda.gov/cdrh/stdsprog.html">www.fda.gov/cdrh/stdsprog.html</a> . Declaration of conformity <a href="http://www.fda.gov/cdrh/devadvice/3145.html#link_9">www.fda.gov/cdrh/devadvice/3145.html#link_9</a> Required Elements for Declaration of Conformity to Recognized Standard <a href="http://www.fda.gov/cdrh/ode/regrecstand.html">www.fda.gov/cdrh/ode/regrecstand.html</a>	X		

Title	Related Information	Present	Inadequate	N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), <a href="http://www.fda.gov/cdrh/k863.html">www.fda.gov/cdrh/k863.html</a>	X		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_10">www.fda.gov/cdrh/devadvice/314312.html#link_10</a>	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) <a href="http://www.fda.gov/cdrh/ode/guidance/361.html">www.fda.gov/cdrh/ode/guidance/361.html</a> For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">www.fda.gov/cdrh/ode/guidance/1216.html</a>	X		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" <a href="http://www.fda.gov/cdrh/g951.html">www.fda.gov/cdrh/g951.html</a>	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices <a href="http://www.fda.gov/cdrh/ode/software.html">www.fda.gov/cdrh/ode/software.html</a>			X
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program <a href="http://www.fda.gov/cdrh/emc">www.fda.gov/cdrh/emc</a> See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			X
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf</a> <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf</a>			X

Title	Related Information	Present	Inadequate	N/A
FORM FDA 3654, <i>Standards Data Report            for 510(k)s -  <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a></i>	<b>Standards Data Report Form – Form 3654</b>  1: No standard used - <b>No Standards Form Required</b>  2: Declaration of Conformity – <b>Yes Standards Form Required</b>  3: Standard but no declaration – <b>Yes Standards Form Required</b>	X		
Kit Certification	Device Advice <a href="http://www.fda.gov/cdrh/ode/odecl874.html">http://www.fda.gov/cdrh/ode/odecl874.html</a>			X

*Last Updated: 9/3/08 – Brandi Stuart*



**DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M**

Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

**Premarket Notification 510(k) Review  
Traditional  
K111289**

Date: August 10, 2011  
To: The Record  
From: Andrew Yang

Office: ODE  
Division: DONED

510(k) Holder: Entellus Medical, Inc.  
Device Name: PathAssist Light Fiber  
Contact: Karen E. Peterson, Vice President Clinical, Regulatory and Quality  
Phone: 763-463-7066  
Mobile: 651-398-4341  
Fax: 763-463-1599  
Email: [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)

**I. Purpose and Submission Summary:**

The 510(k) holder would like to introduce PathAssist Light Fiber into interstate commerce.

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: <u>Prescription</u> or OTC)	X		
Truthful and Accuracy Statement	X		
<u>510(k) Summary</u> or 510(k) Statement	X		
Standards Form	X		

**III. Device Description**

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X		

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a nominal fiber working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm. See photo below.

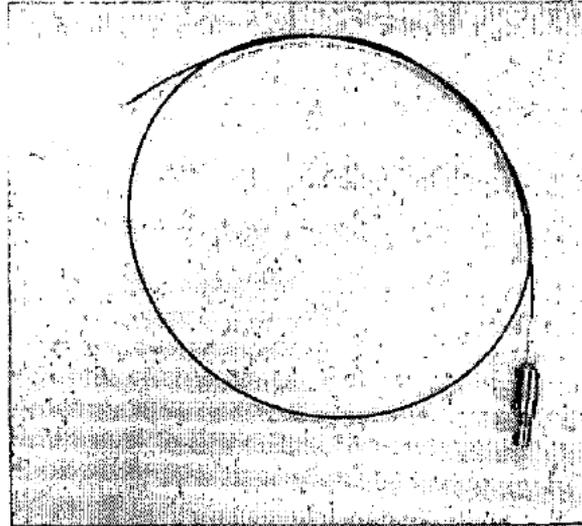
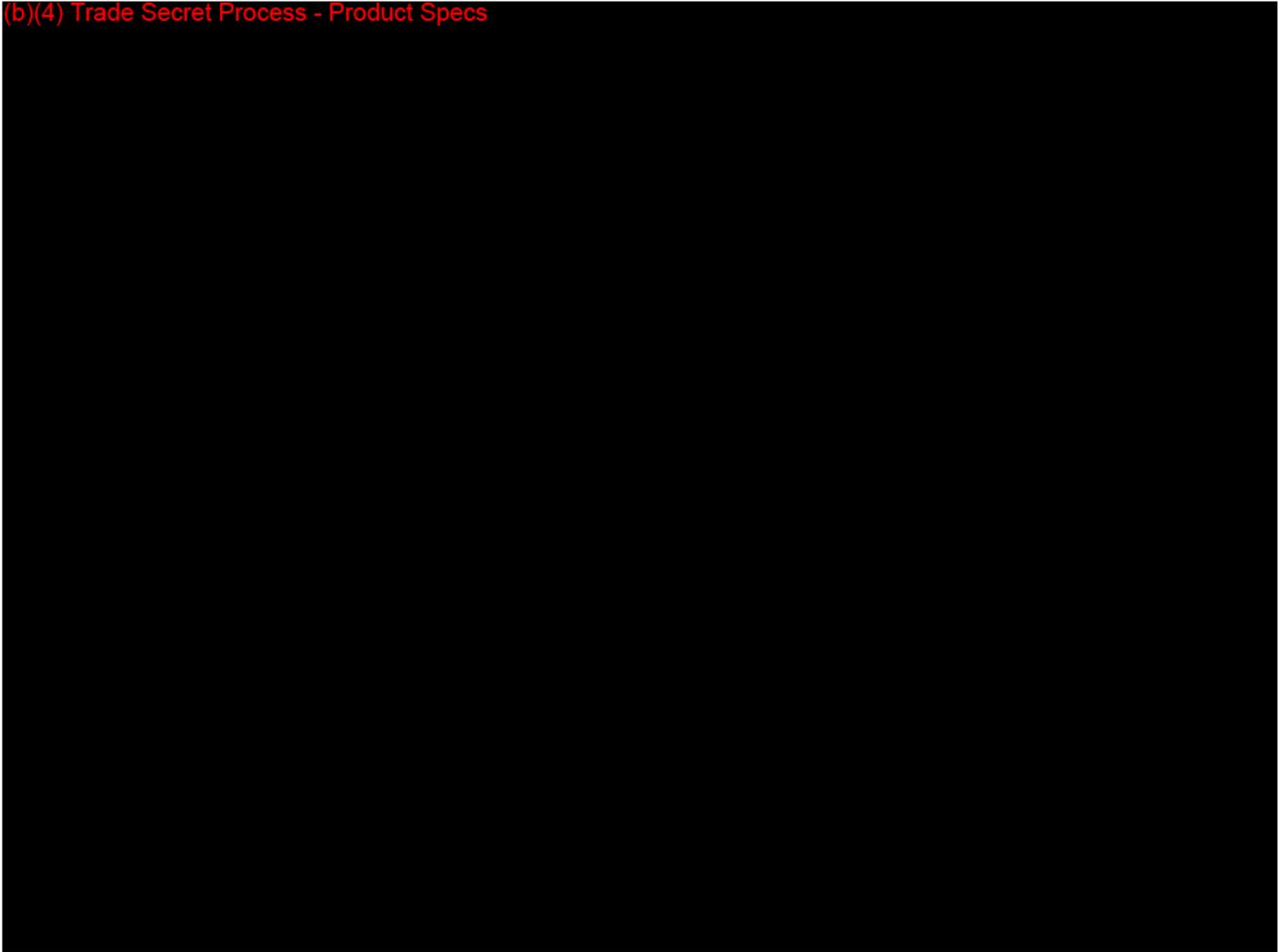


Figure 13-1 PathAssist Light Fiber

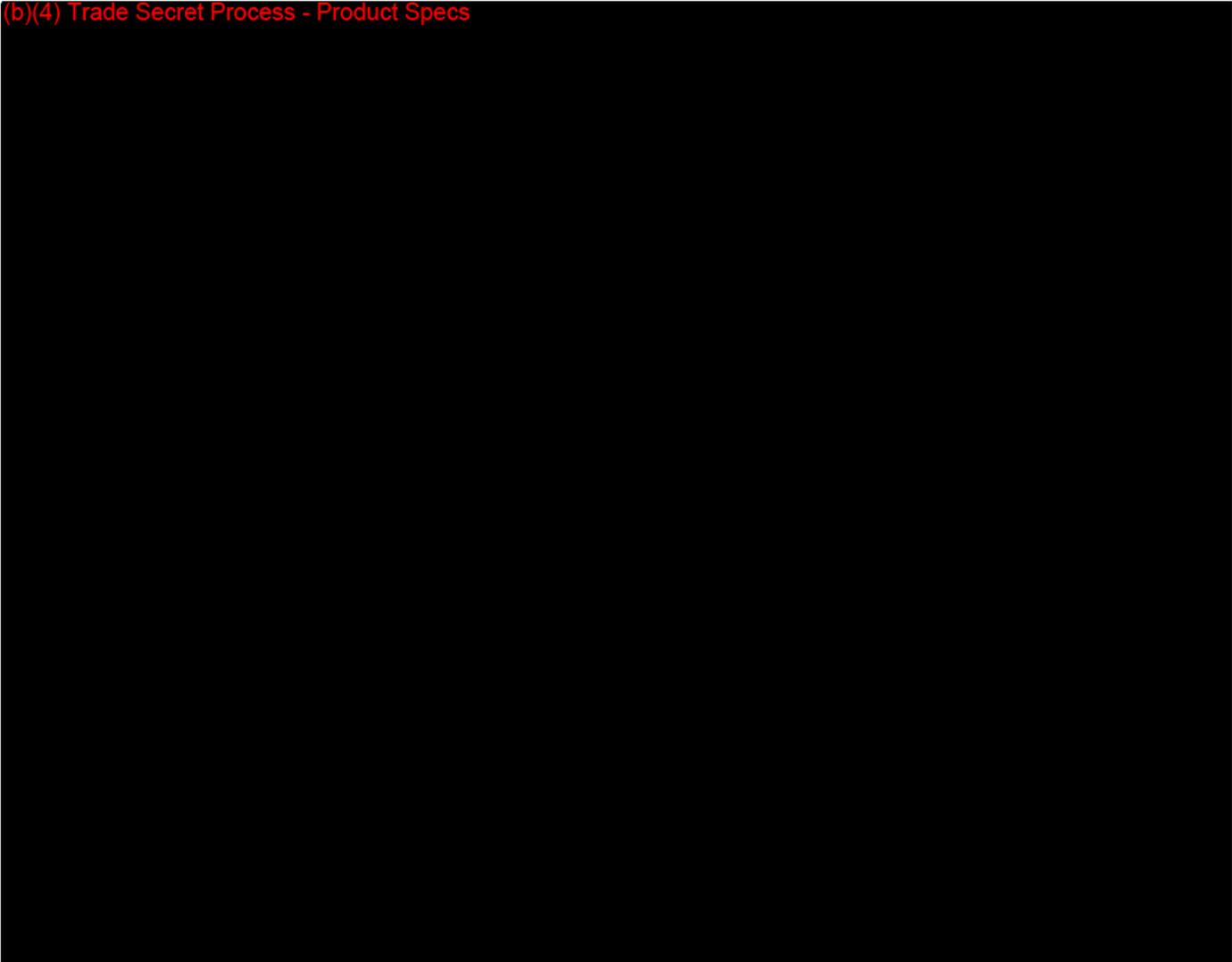
IV. Indications for Use

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

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



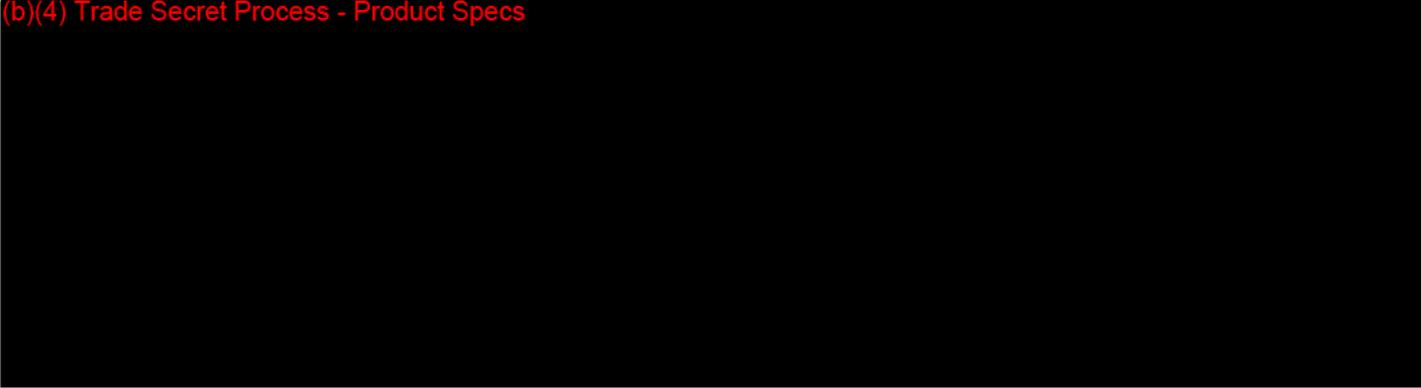
(b)(4) Trade Secret Process - Product Specs



VI. Labeling

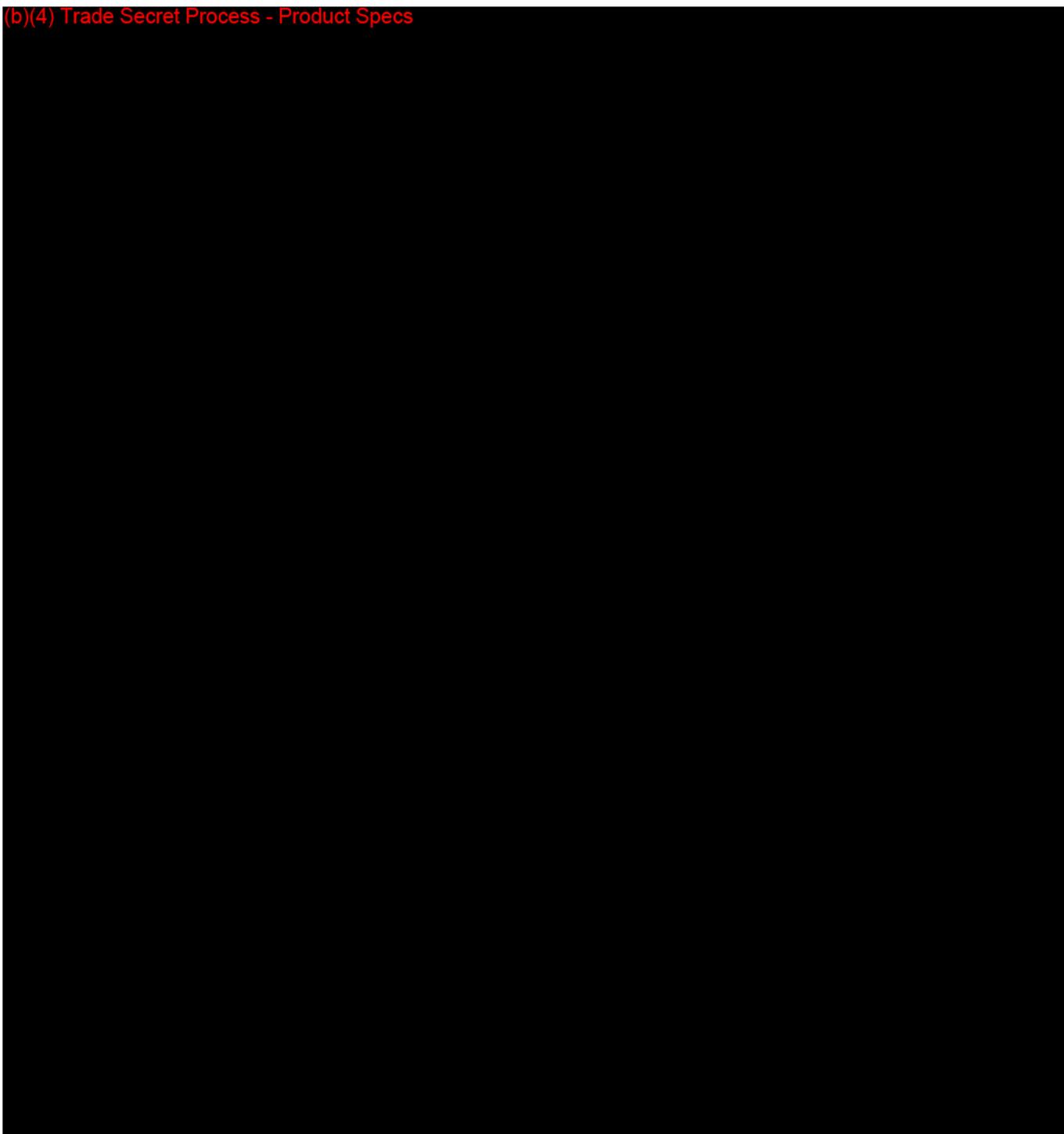
15. Proposed Labeling

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



VII. Sterilization/Shelf Life/Reuse

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

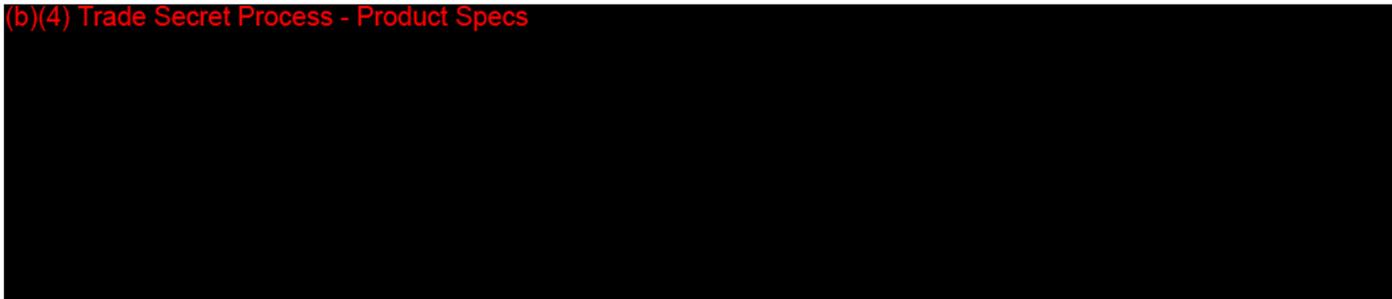


(b)(4) Trade Secret Process - Product Specs

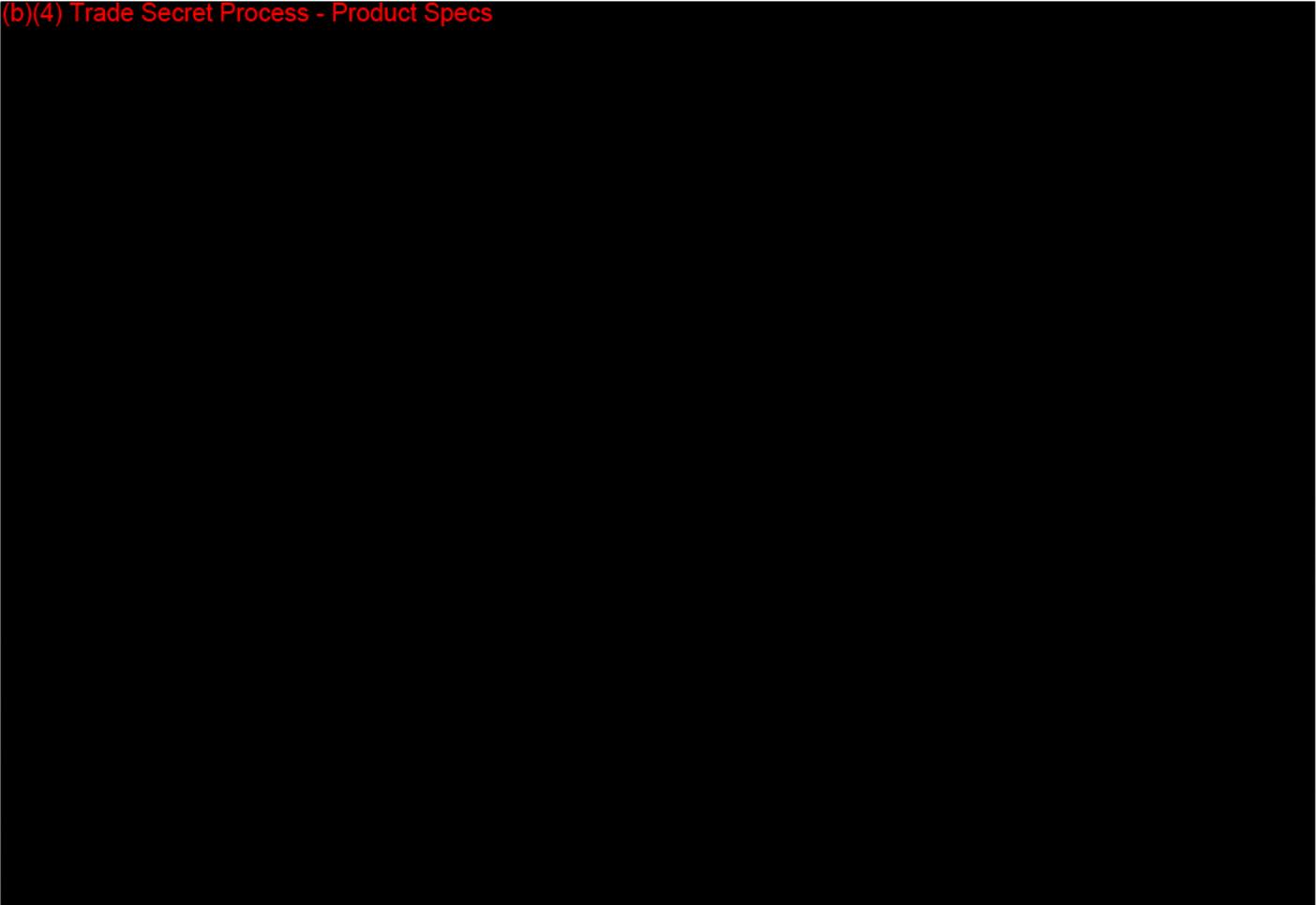


**VIII. Biocompatibility**

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



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



IX. Software

n/a

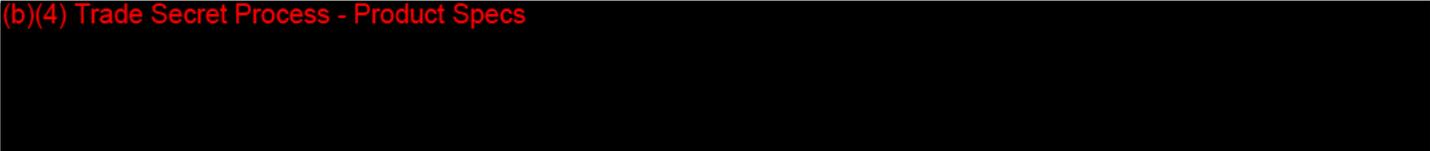
X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

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

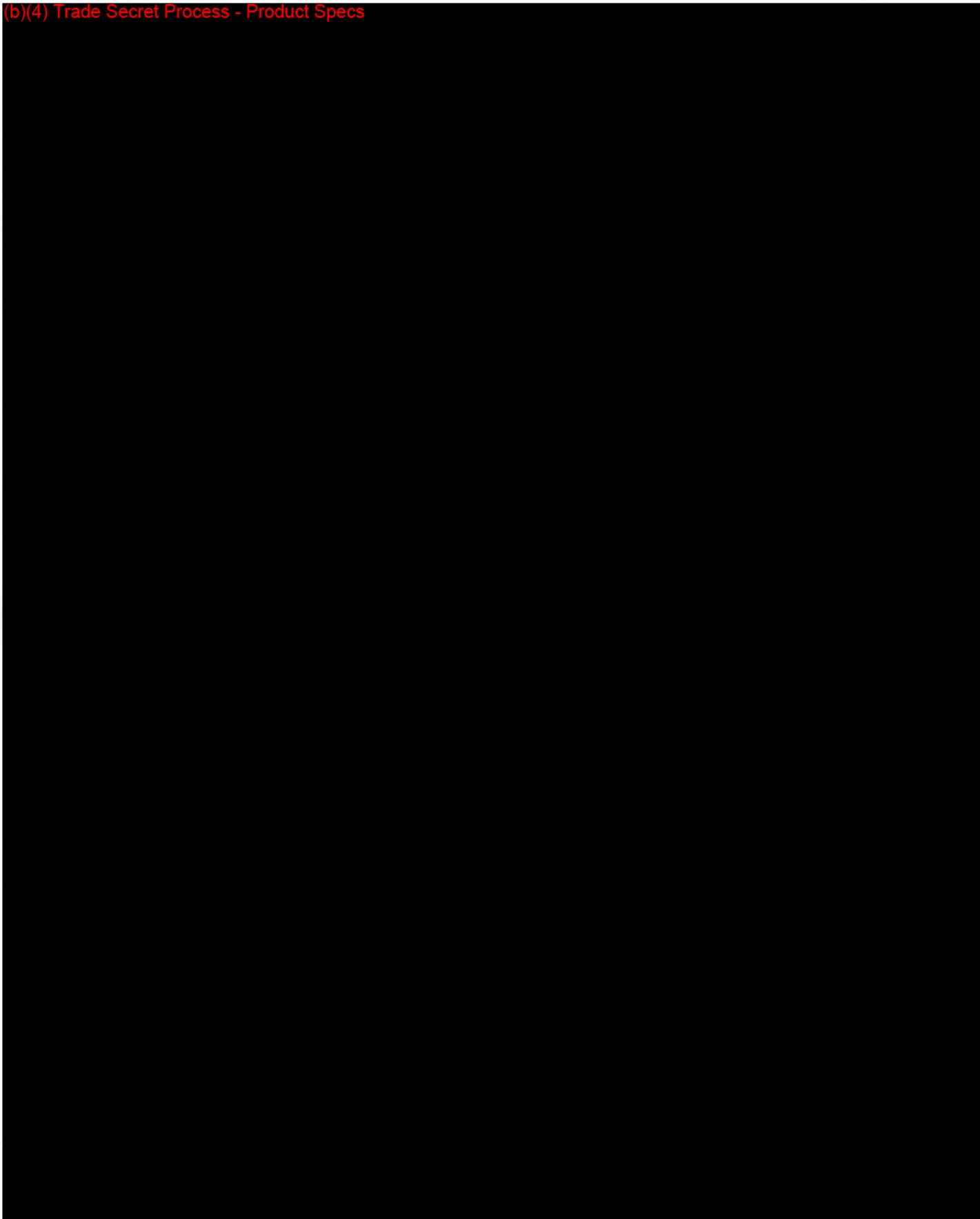


XI. Performance Testing – Bench

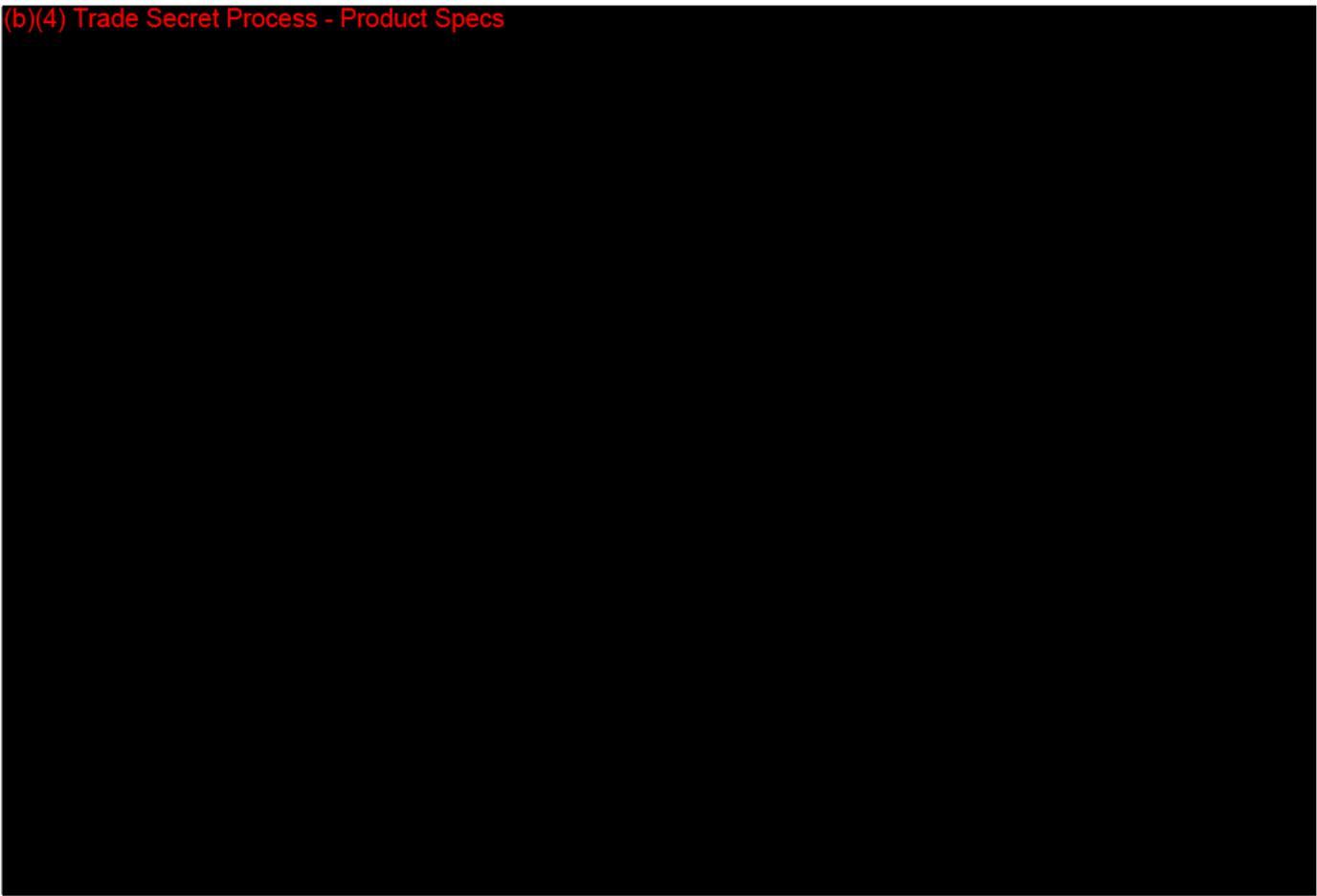
(b)(4) Trade Secret Process - Product Specs



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



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



**XII. Performance Testing – Animal**

n/a

**XIII. Performance Testing – Clinical**

n/a

**XIV. 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?		X	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision: <b>TH</b>

Note: See

[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

n/a

2. Explain why there is or is not a new effect or safety or effectiveness issue:

n/a

3. Describe the new technological characteristics:

n/a

4. Explain how new characteristics could or could not affect safety or effectiveness:

n/a

5. Explain how descriptive characteristics are not precise enough:

n/a

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

*n/a*

7. Explain why existing scientific methods can not be used:

*n/a*

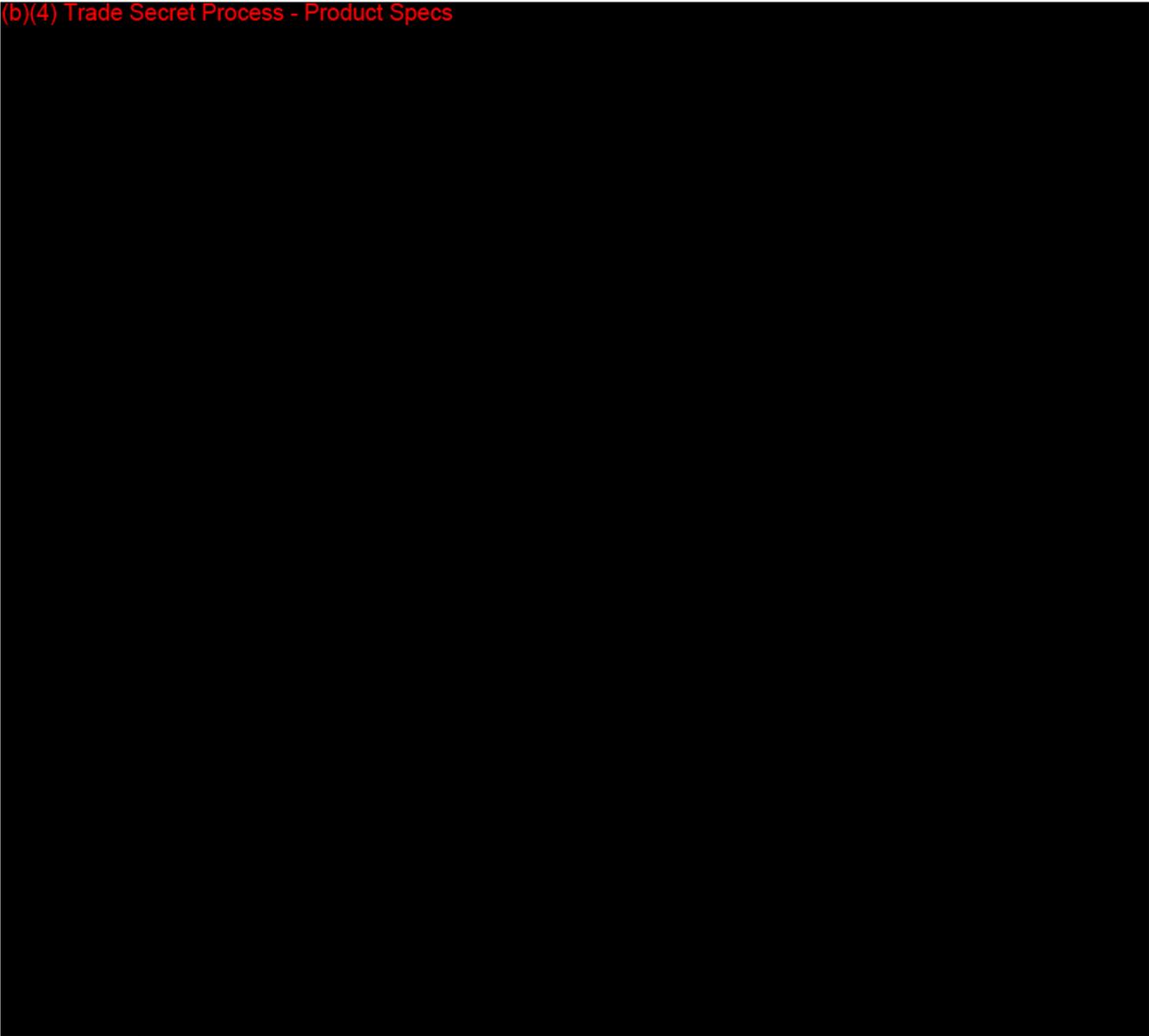
8. Explain what performance data is needed:

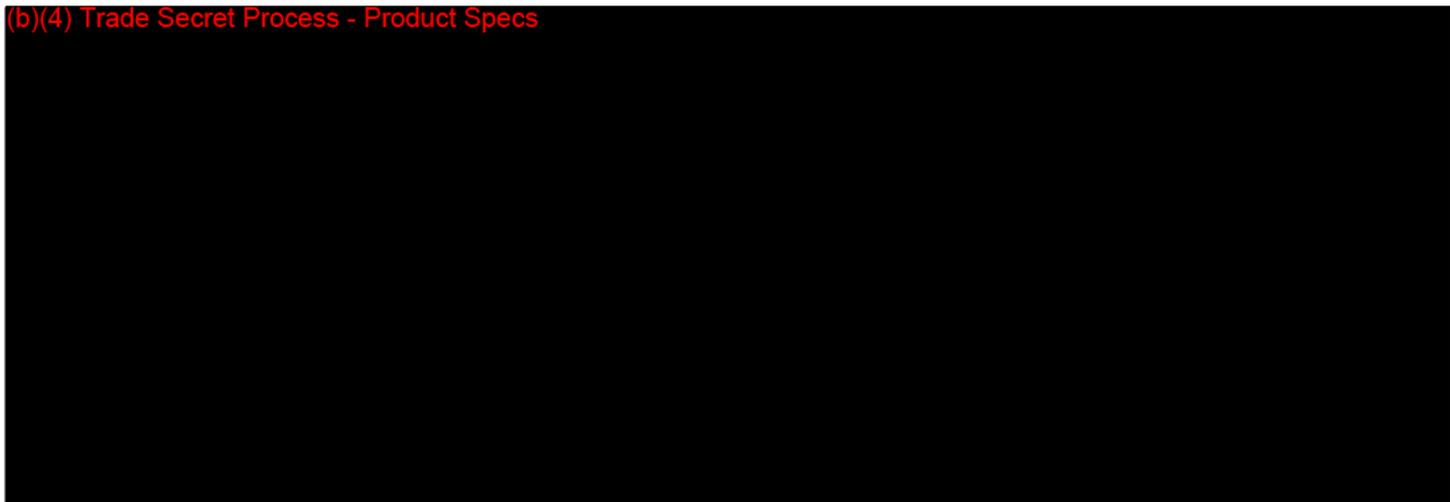
*n/a*

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

*n/a*

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





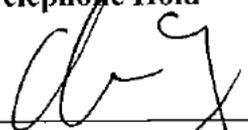
**XVI. Advisory**

n/a

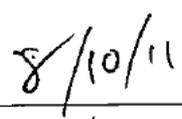
**XVII. Recommendation**

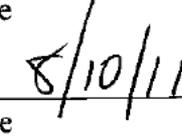
Regulation Number: 21 CFR 874.4420  
Regulation Name: ENT manual surgical instrument  
Regulatory Class: Class I  
Product Code: LRC

**TH – Telephone Hold**

  
\_\_\_\_\_  
Reviewer

  
\_\_\_\_\_  
Branch Chief

  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Date



**Memorandum**

**Mechanical Engineering / Electromagnetic Compatibility & Electrical Safety**

Date: July 13, 2011

To: The Record

From:

  
LT Andrew Yang, BE, ME, EIT  
Biomedical Engineer  
Ear Nose and Throat device Branch (ENTB)  
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices

Subject: K111763

Device: Entellus Medical's PathAssist Light Fiber

Recommendation: **AI – Request additional information**

**INDICATIONS FOR USE (IFU)**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

**DEVICE DESCRIPTION**

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a nominal fiber working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm. See photo below.

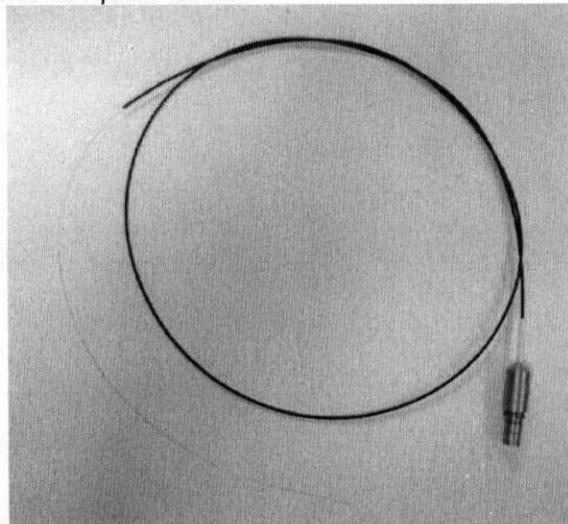


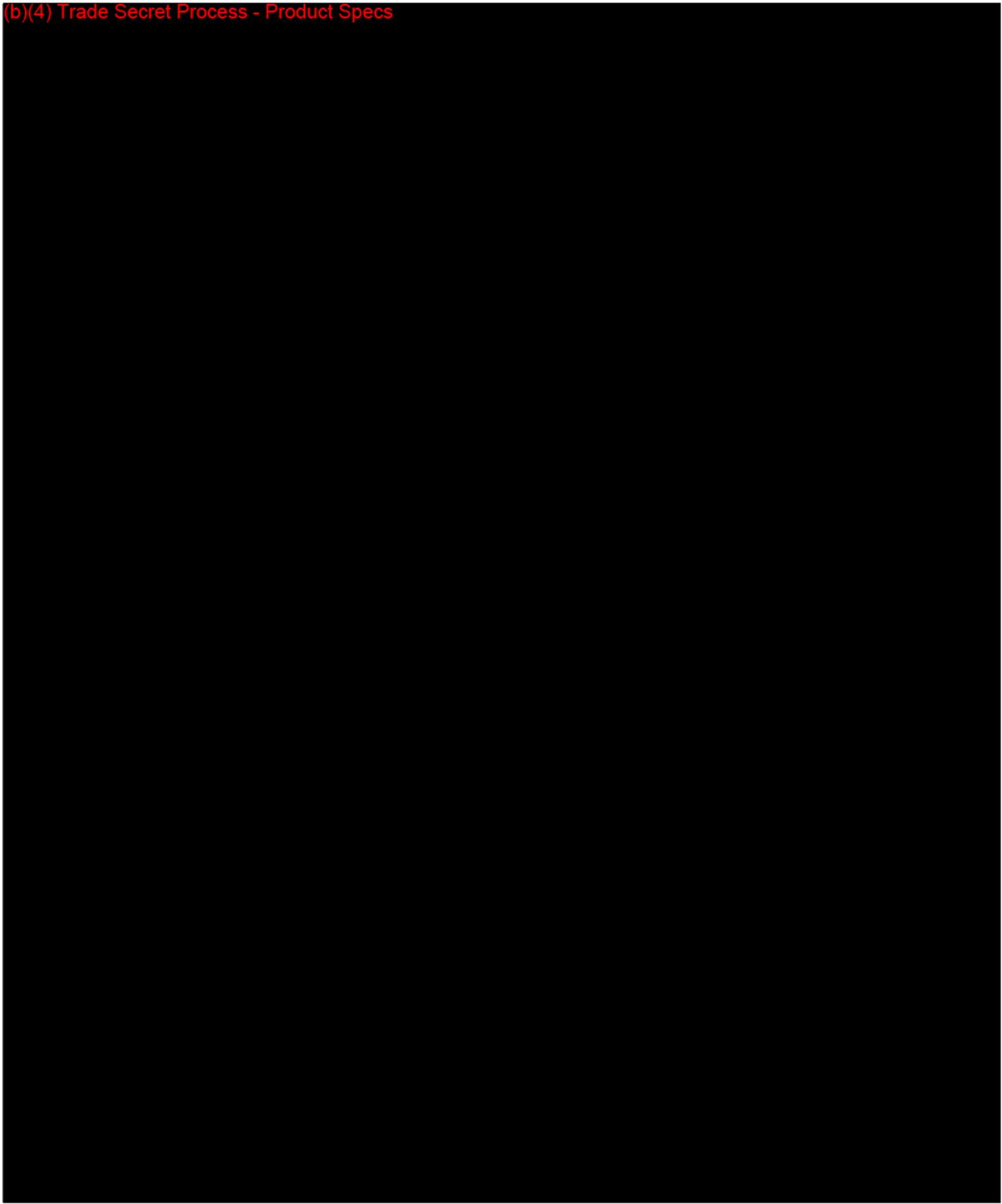
Figure 13-1 PathAssist Light Fiber

Note:

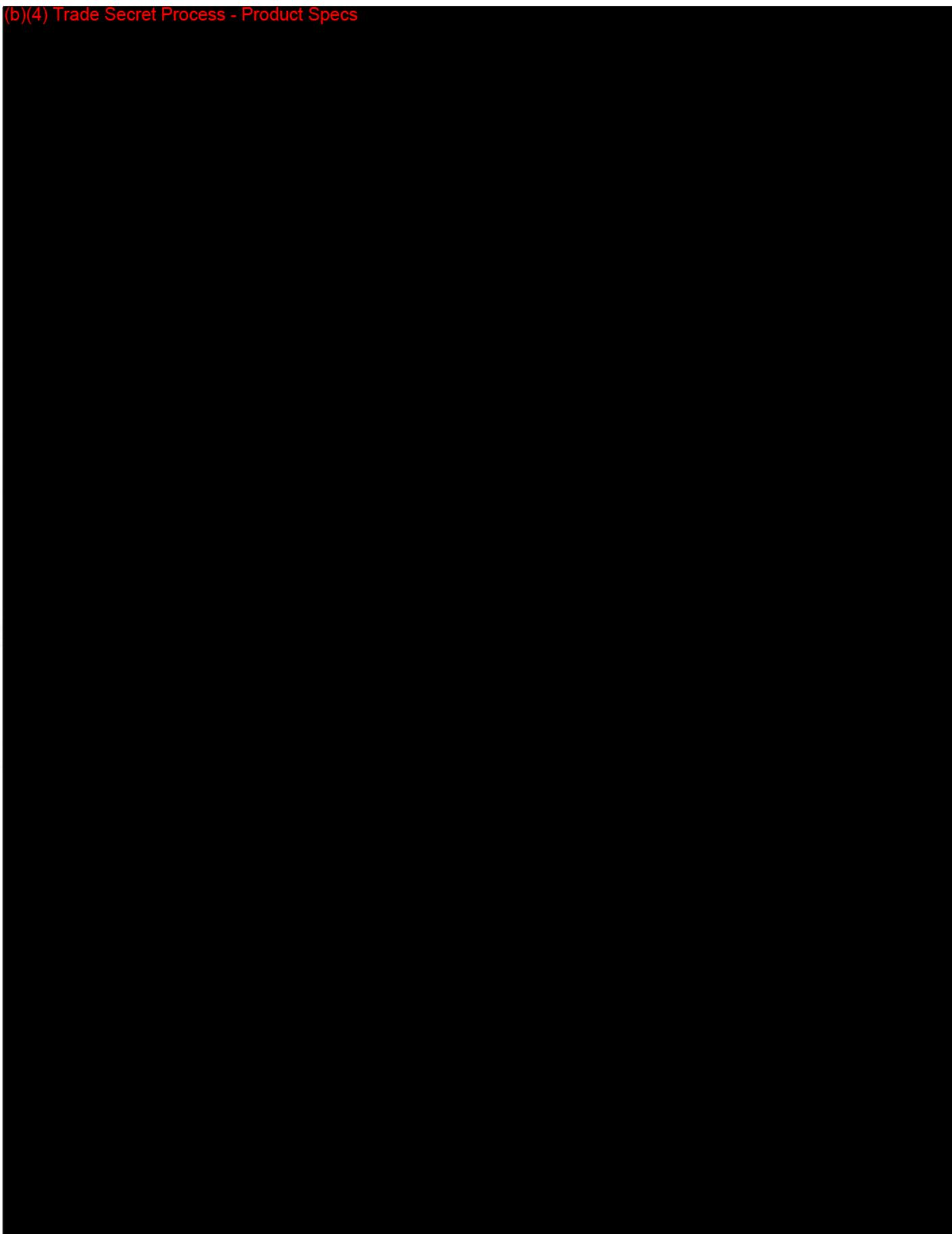
Arial font indicates sponsor language

Times New Roman font indicates reviewer language

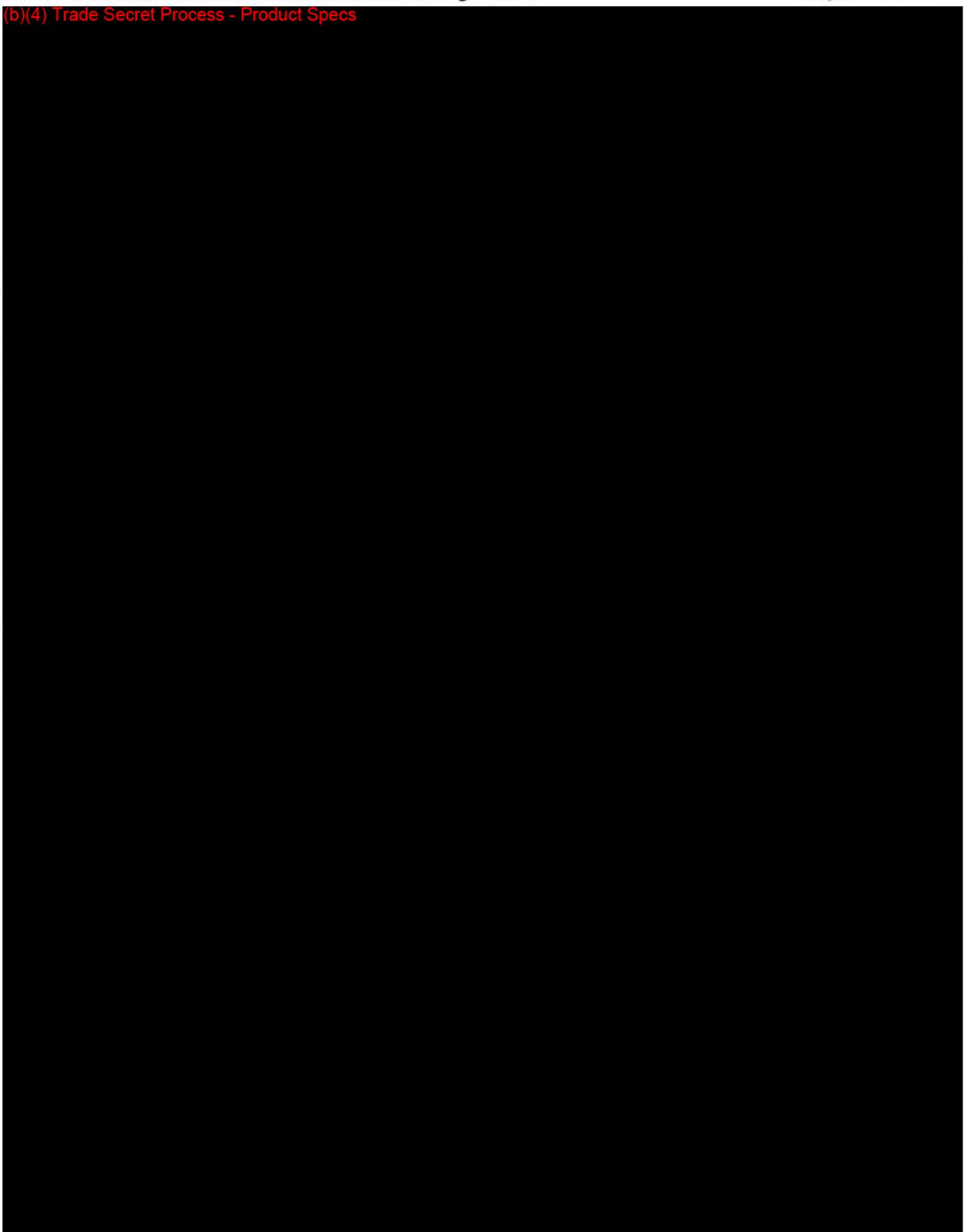
(b)(4) Trade Secret Process - Product Specs



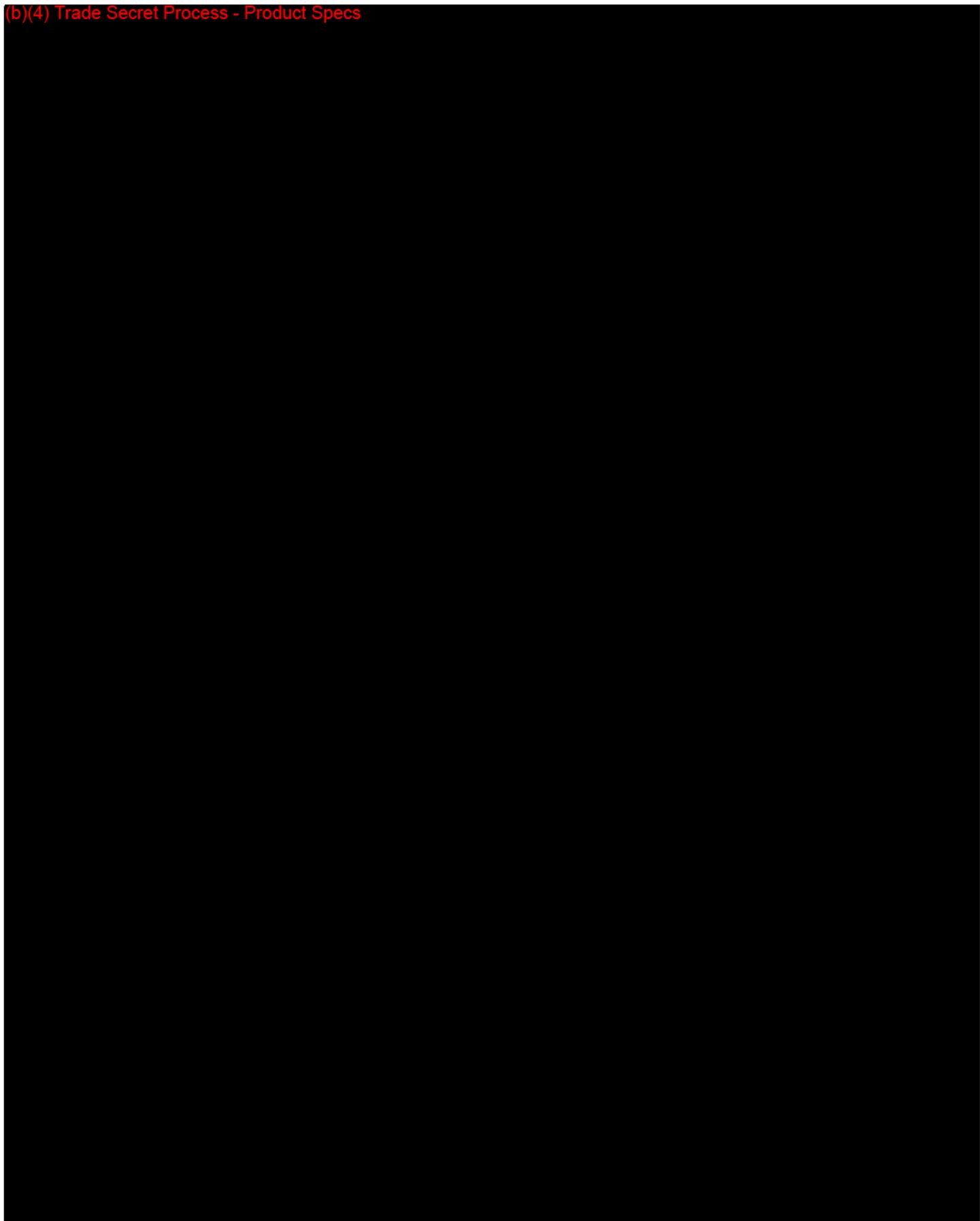
(b)(4) Trade Secret Process - Product Specs



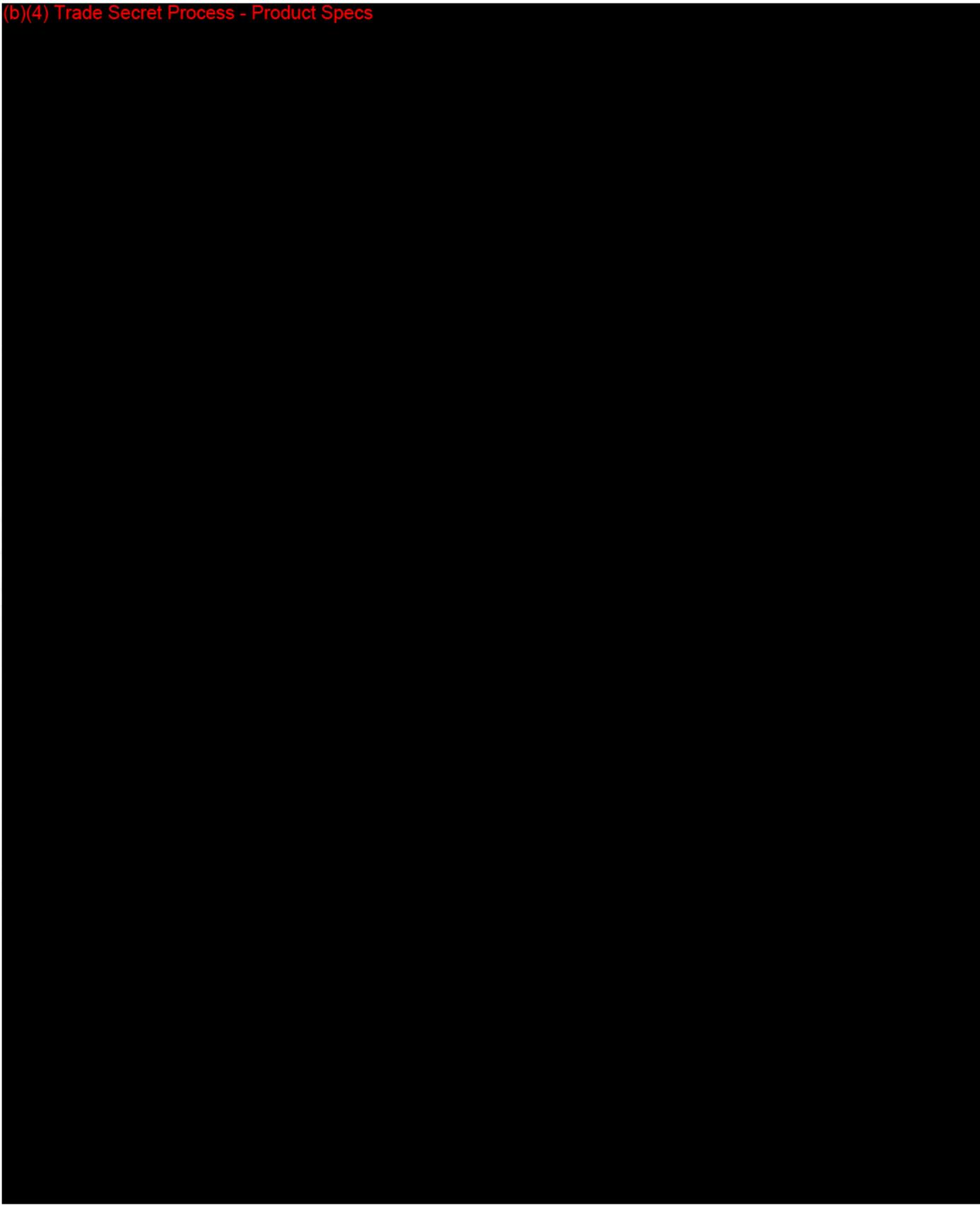
(b)(4) Trade Secret Process - Product Specs



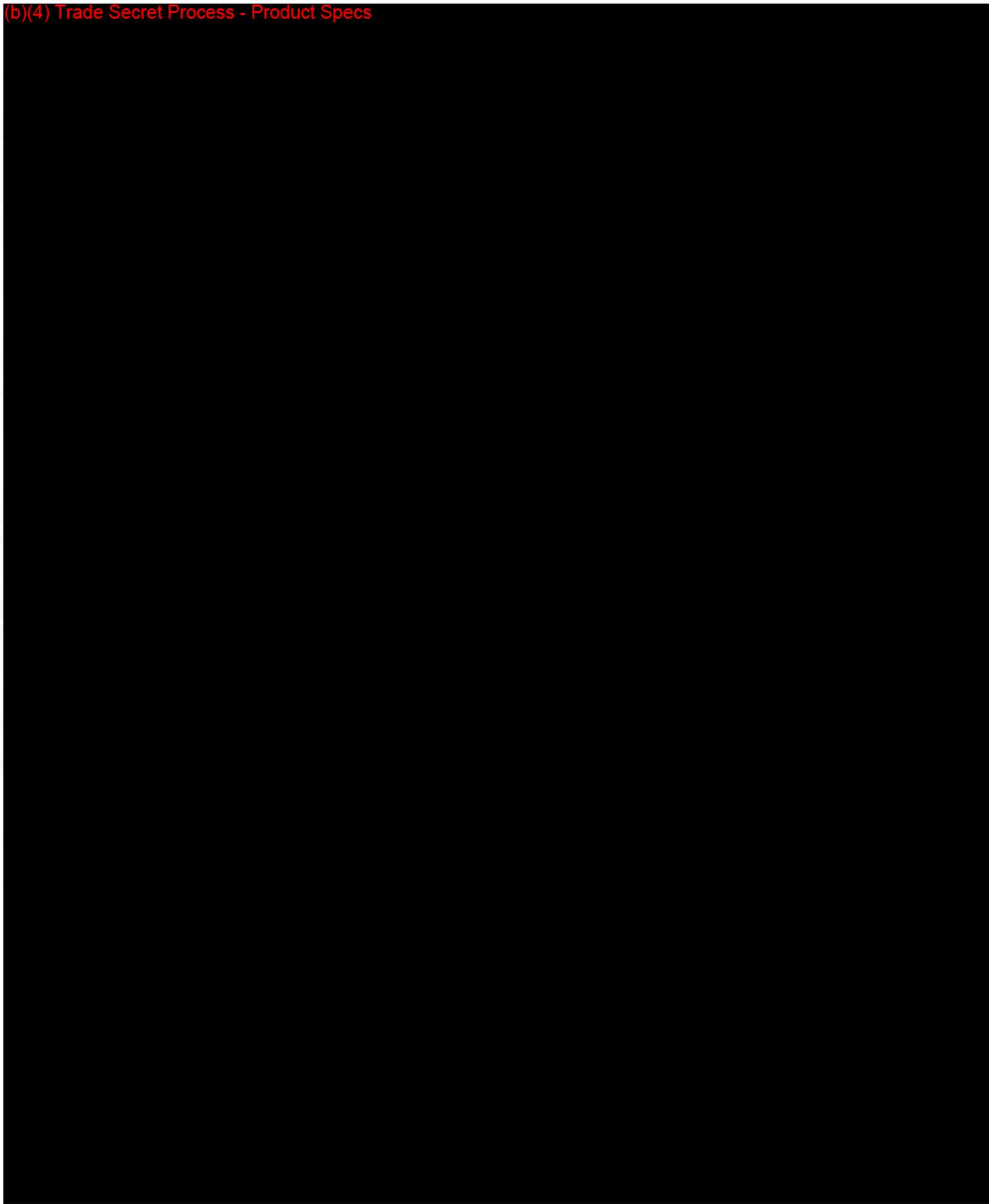
(b)(4) Trade Secret Process - Product Specs



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



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

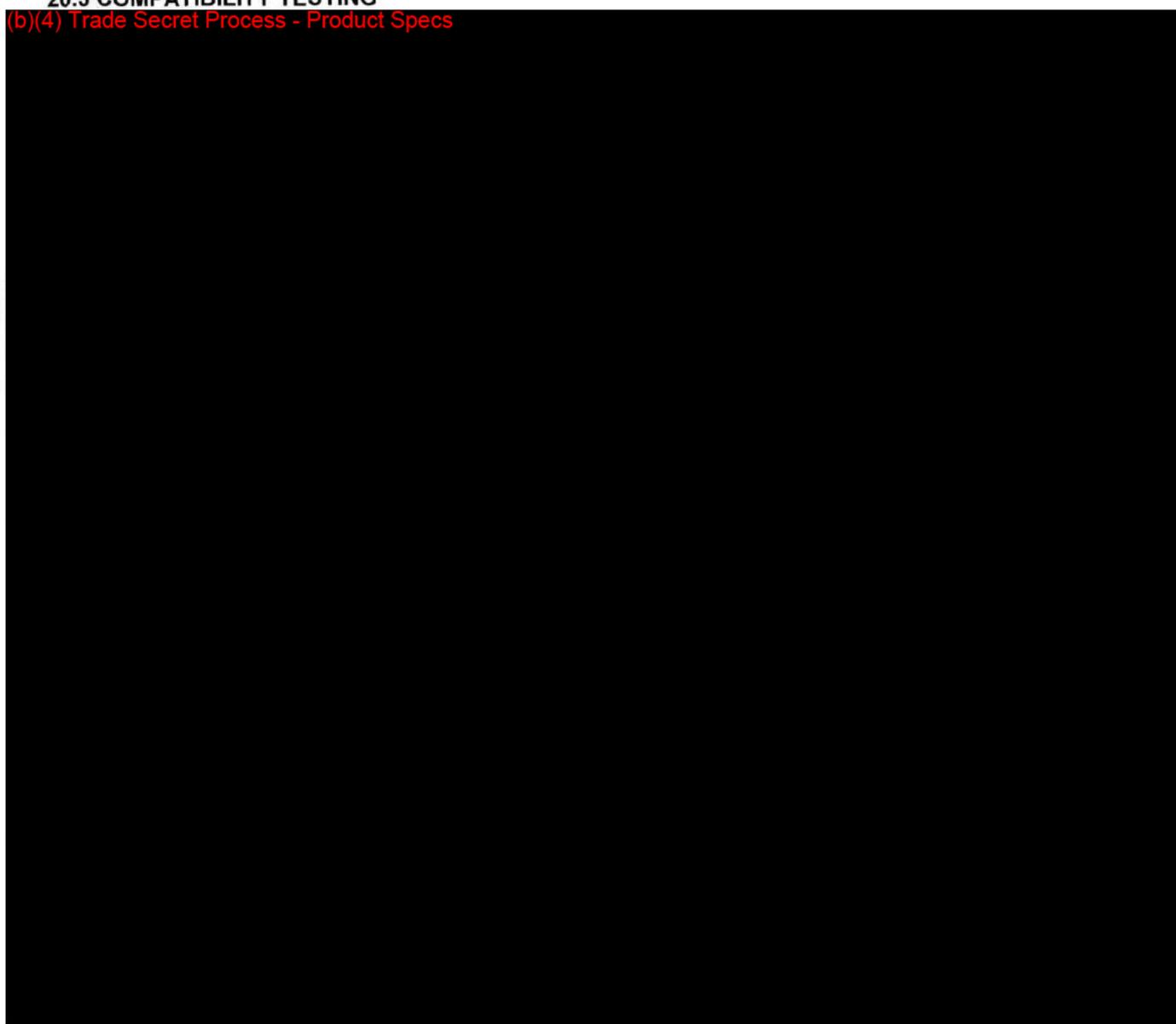


(b)(4) Trade Secret Process - Product Specs



**20.3 COMPATIBILITY TESTING**

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



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

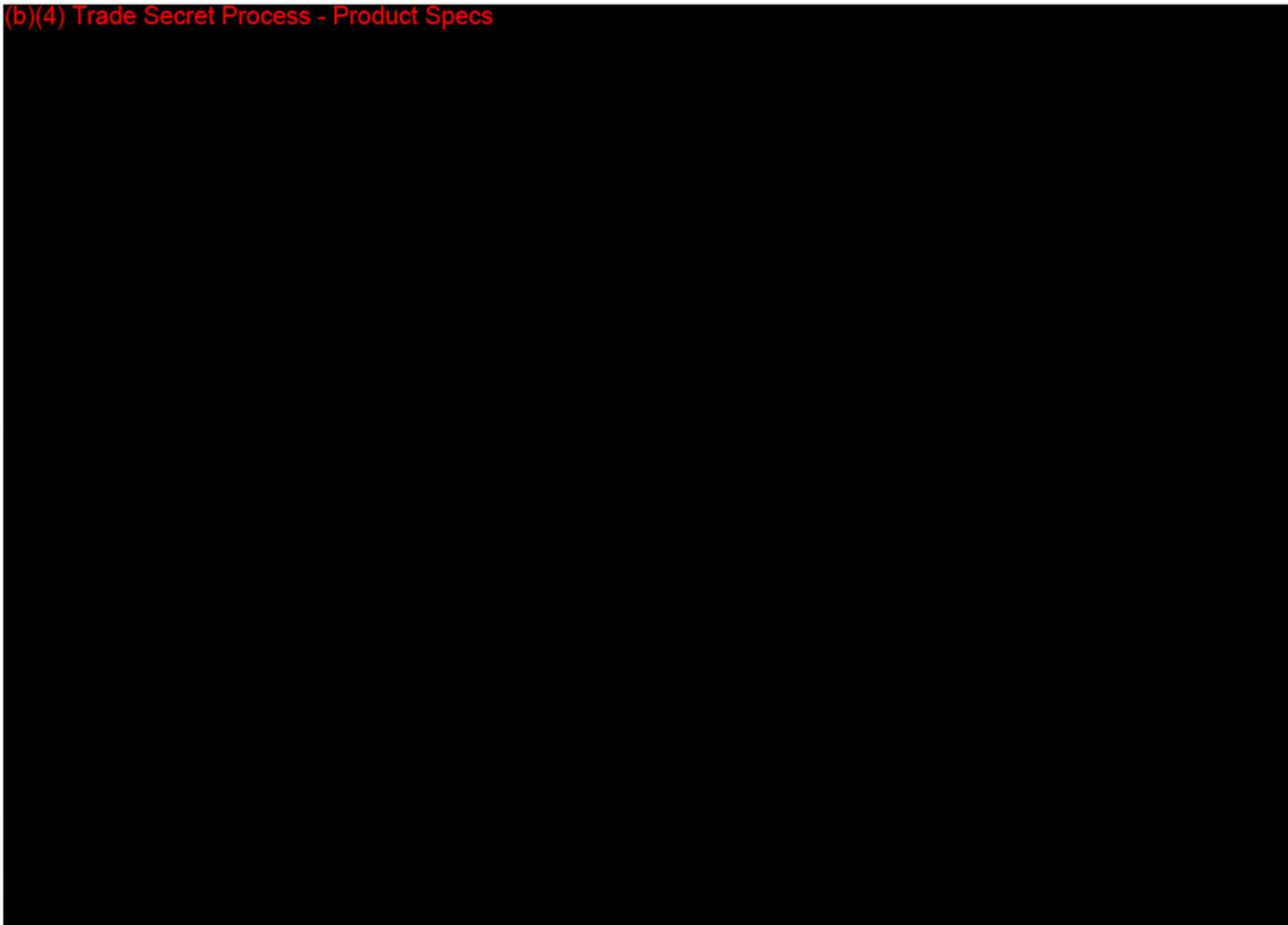


**20.4 PACKAGING TESTING**

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

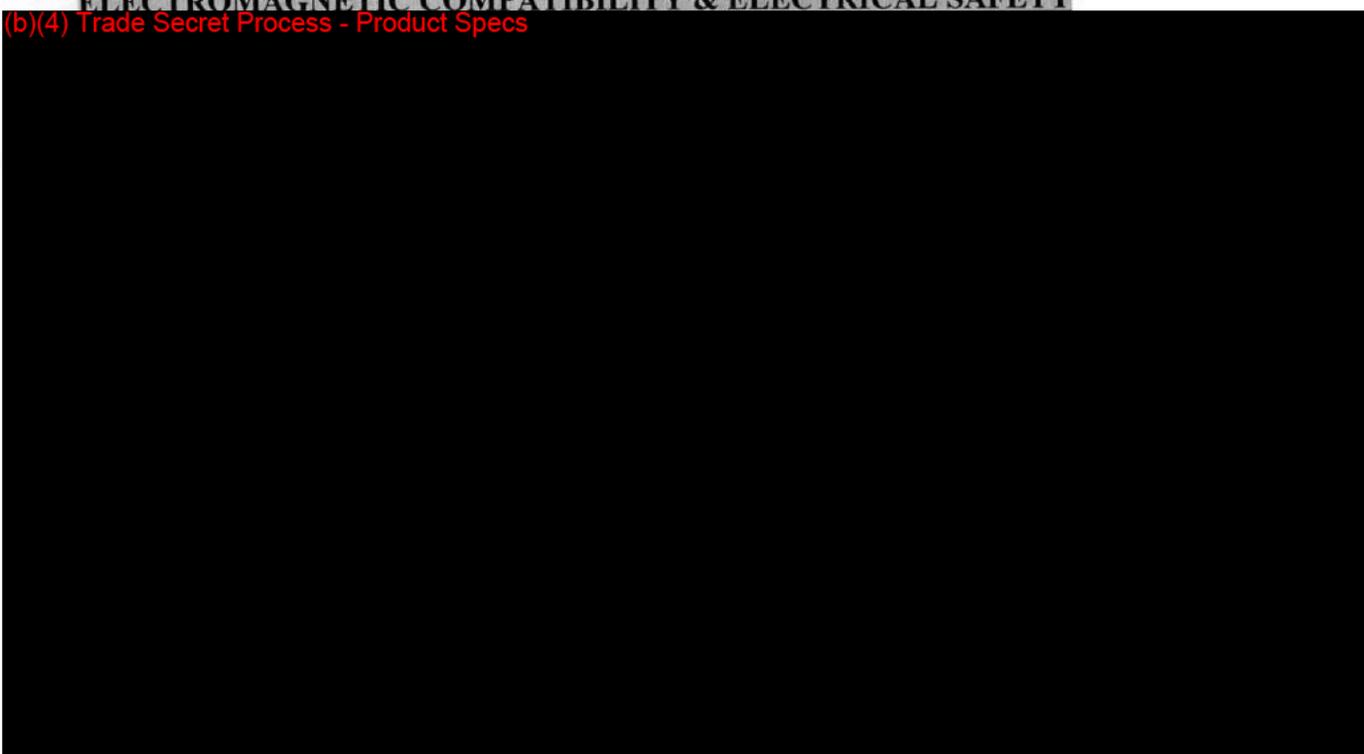


(b)(4) Trade Secret Process - Product Specs

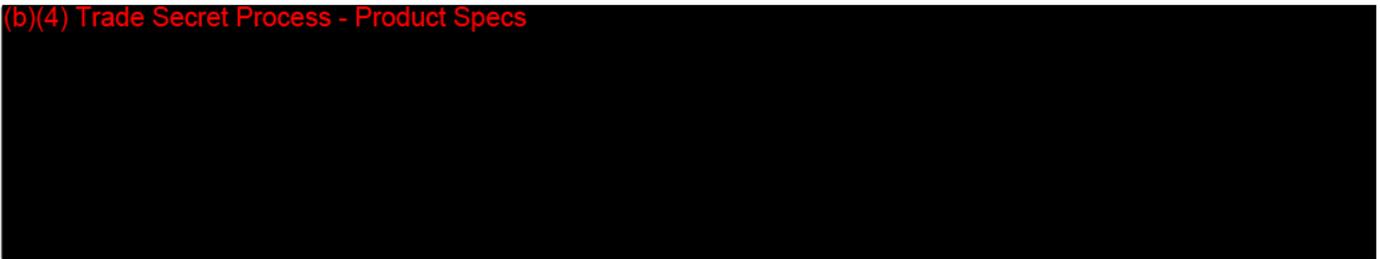


**ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY**

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



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





DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
ODE / DONED / ENTB  
WO66 Rm 2574  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**TO:** Lt. Andrew Yang – team leader

**FROM:** Susan Rudy, MSN, CRNP, CORLN  
Nurse Consultant and Family Nurse Practitioner, ENTB

*S. Rudy CRNP  
8/4/2011*

**DATE:** 8/2/2011

**RE:** Sterility Review – Traditional 510(k)  
K111763 Entellus Medical PathAssist Light Fiber (Model PLF)  
Includes FDA interactive query from 8/2/2011 with Entellus' responses on 8/3/2011

**RECOMMENDATION:** SE

---

**Purpose / History:**

This application is for a new device.

**Regulatory**

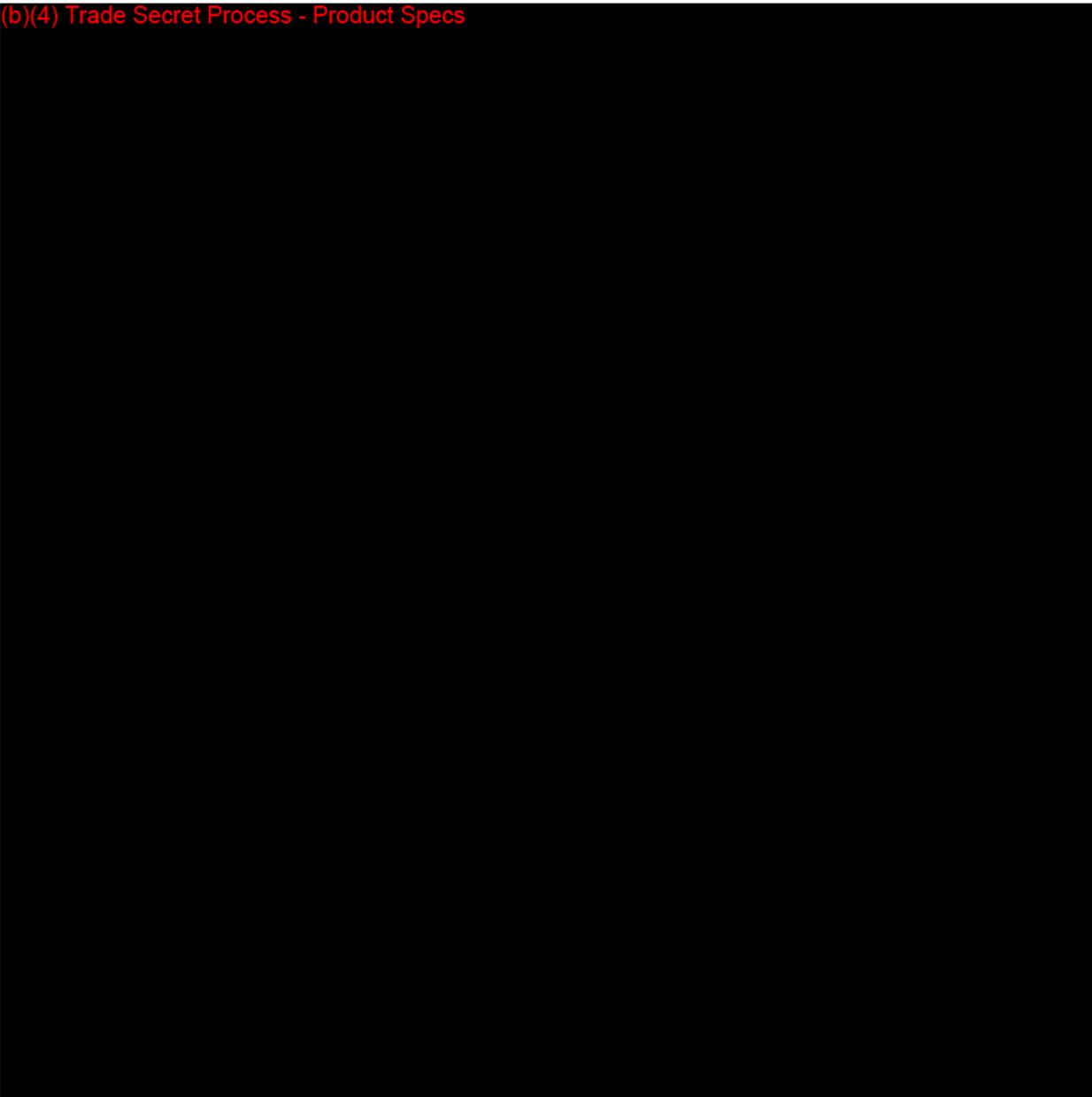
21 CFR 874.4420  
Product Code LRC  
Class I

**Indications for Use**

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

**Device Description (from 510(k) summary)**

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



### 13.1 GENERAL DESCRIPTION

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a nominal fiber working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm. See photo below.

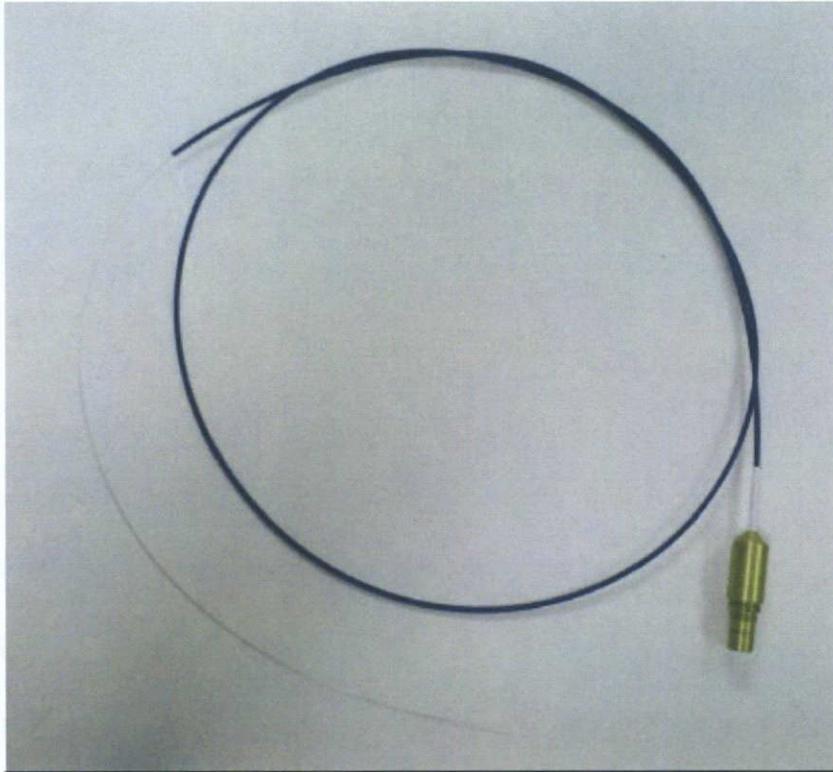
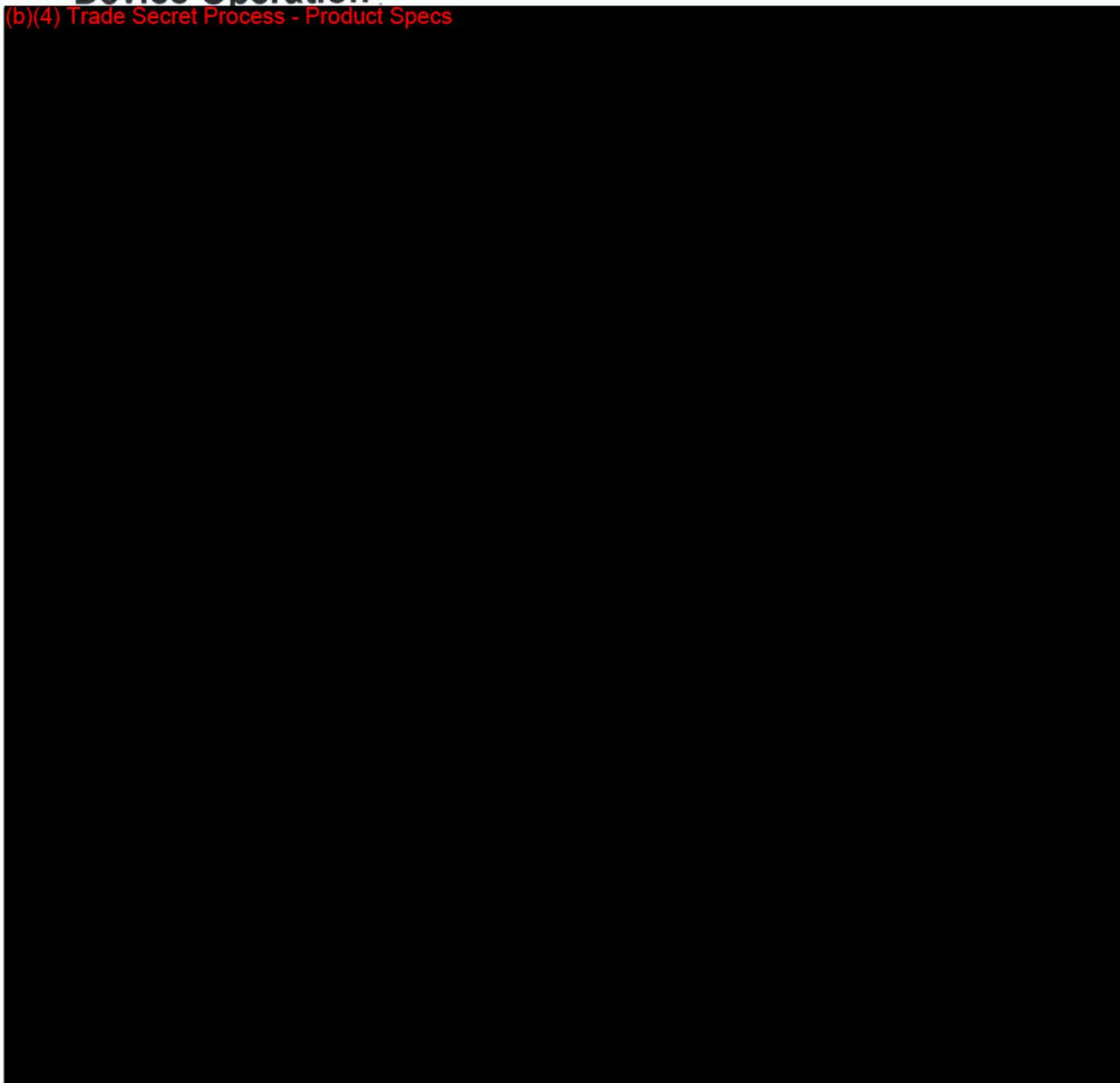


Figure 13-1 PathAssist Light Fiber

Synonyms for the PathAssist Light Fiber = Disposable light fiber  
Synonyms for the Light post = Fiber Adapter

## Device Operation

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



## Materials

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



## Standards

- Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 30, 2002.
- ISO 11135-1: 2007 Sterilization of health care products - ethylene oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals.
- ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity.
- ISO 10993-1: 2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing.
- ISO 11607: 2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems; & Part 2: Validation requirements for forming sealing and assembly processes.
- ASTM D4169: 2009 Standard practice for performance testing of shipping containers and systems.
- ASTM F1980-07: 2007 Standard guide for accelerated aging of sterile barrier systems for medical devices.
- ASTM F88-00: 2009 Standard test method for seal strength of flexible barrier materials.
- ASTM F2096: 2004 Standard test method for detecting gross leaks in medical packaging by internal pressurization (bubble test).

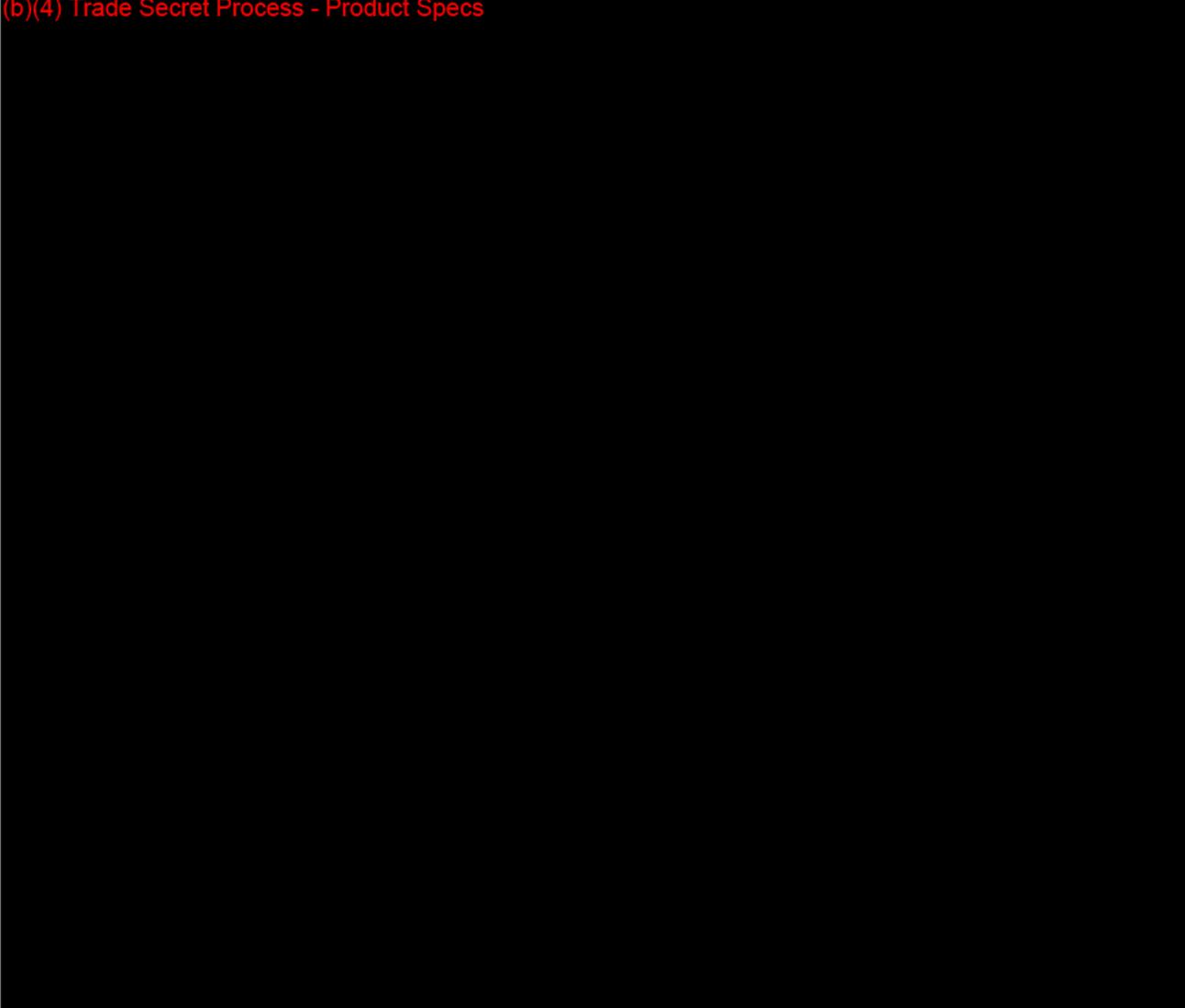
## Predicate Devices:

K071845 Acclarent Inc.'s Relieva Luma Sinus Illumination System

See comparison in grid below

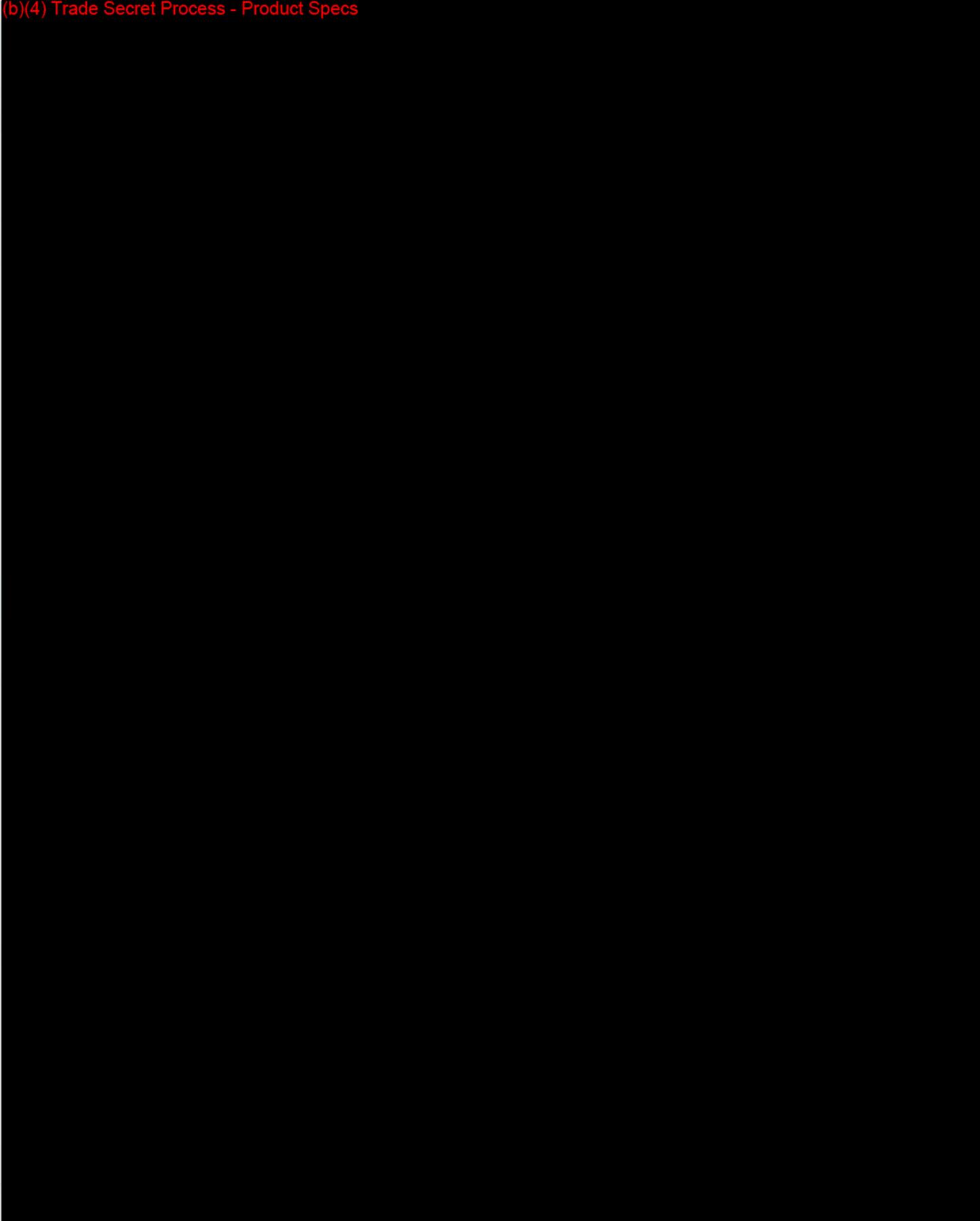
## Packaging

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



## Proposed Labeling

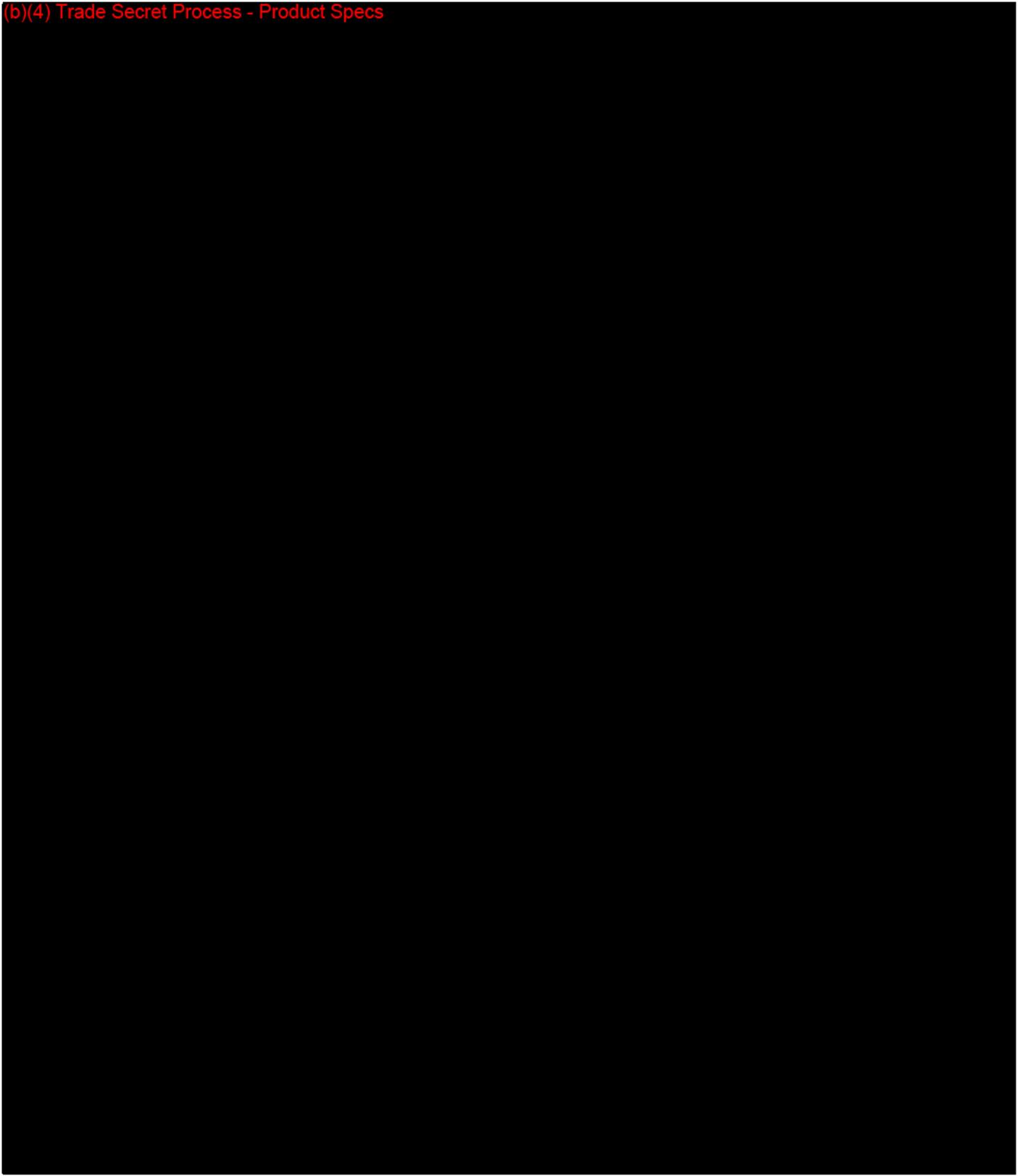
(b)(4) Trade Secret Process - Product Specs



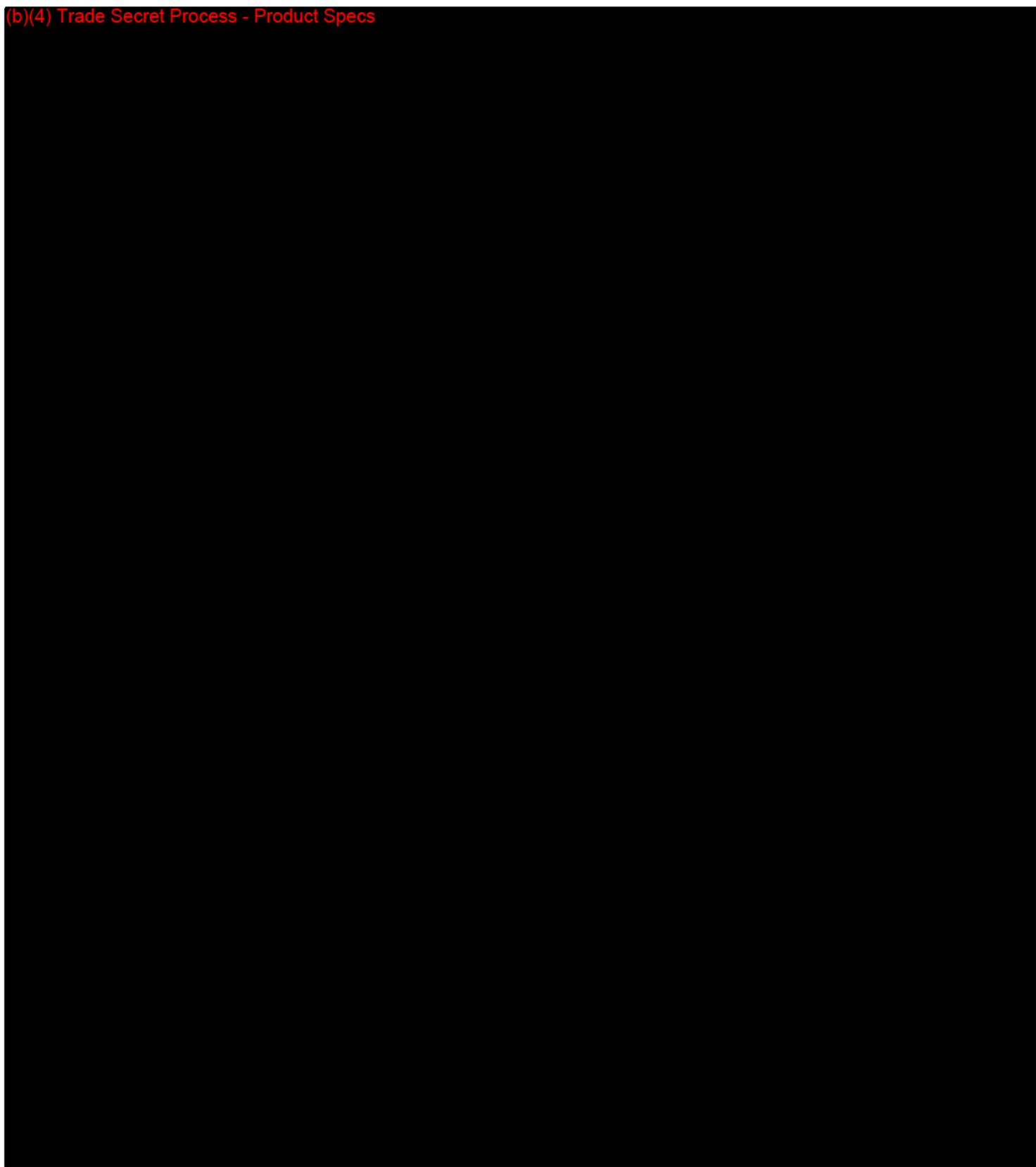
(b)(4) Trade Secret Process - Product Specs



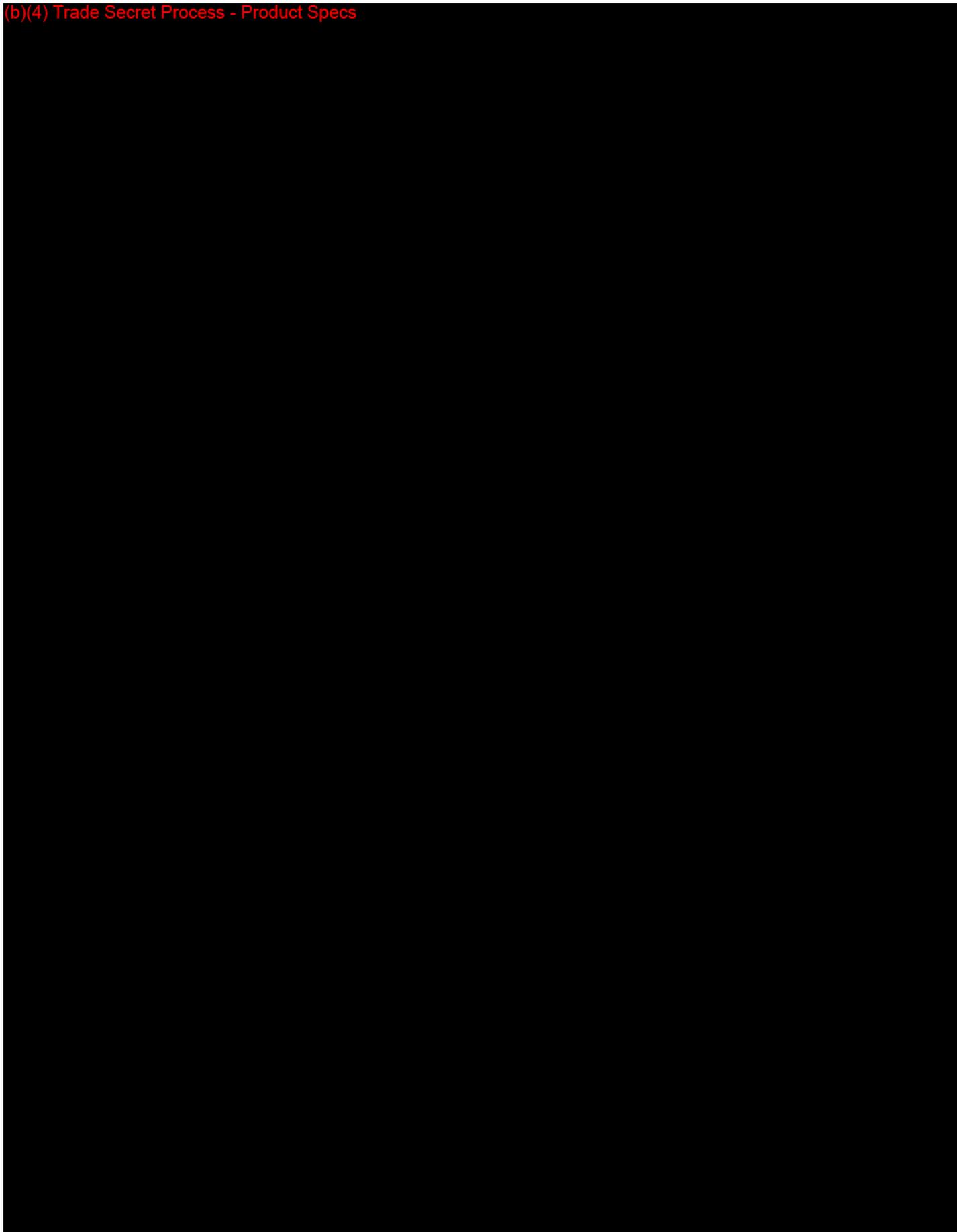
(b)(4) Trade Secret Process - Product Specs



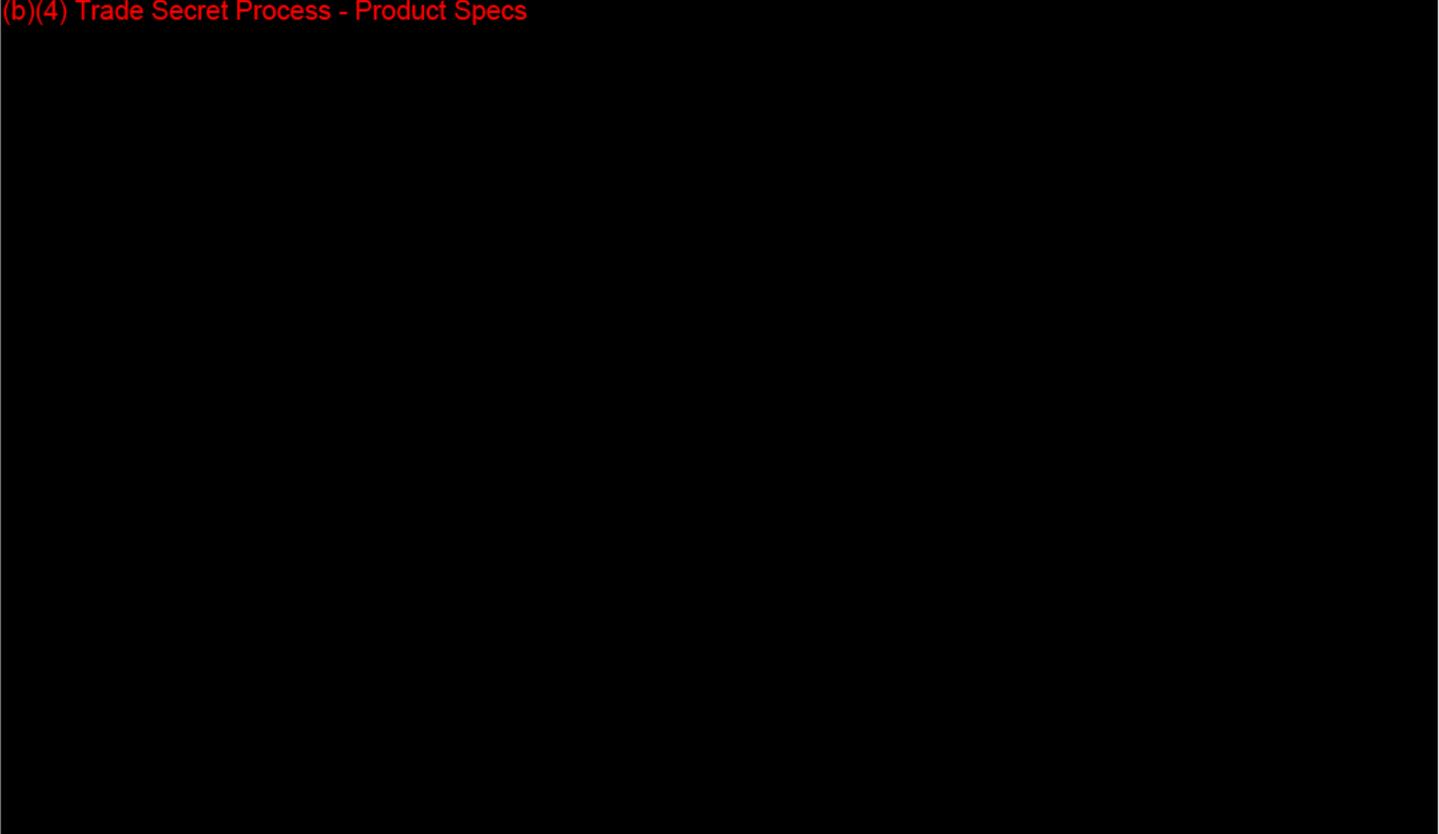
(b)(4) Trade Secret Process - Product Specs



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



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



**END OF REVIEW**

---

**Recommendation: SE**

Path Assist Light Fiber  
K111763  
Entellus Medical

**OFFICE OF DEVICE EVALUATION**  
**510 (k) Clinical Review**  
**K111763**

**From:** Anjum Khan, M.D., MPH  
Medical Officer, ENTB/DONED/ODE

**To:** Andrew Yang,  
Biomedical Engineer, ENTB/DONED/ODE

**Cc:** Sirinivas Nandkumar, Ph.D  
Branch Chief, ENTB/DONED/ODE

**Cc:** Eric Mann, M.D., PhD  
Clinical Deputy Director, Division of Ophthalmic/ENT  
ODE/DONED

**Date:** 07-22-11

**Subject:** **K111763**  
**Path Assist Light Fiber**

*A. KHAN*  
7.22.11

---

**Purpose:**

Entellus Medical is providing a Traditional 510(k) Premarket Notification for the PathAssist Light Fiber.

**Indications for Use:**

The PathAssist Light Fiber is intended to locate, illuminate within and transilluminate across nasal and sinus structures in adults aged 18 and over.

**Predicate Device:**

Acclarent Relieva Luma Sinus Illumination System [K071845]

**Device Description:**

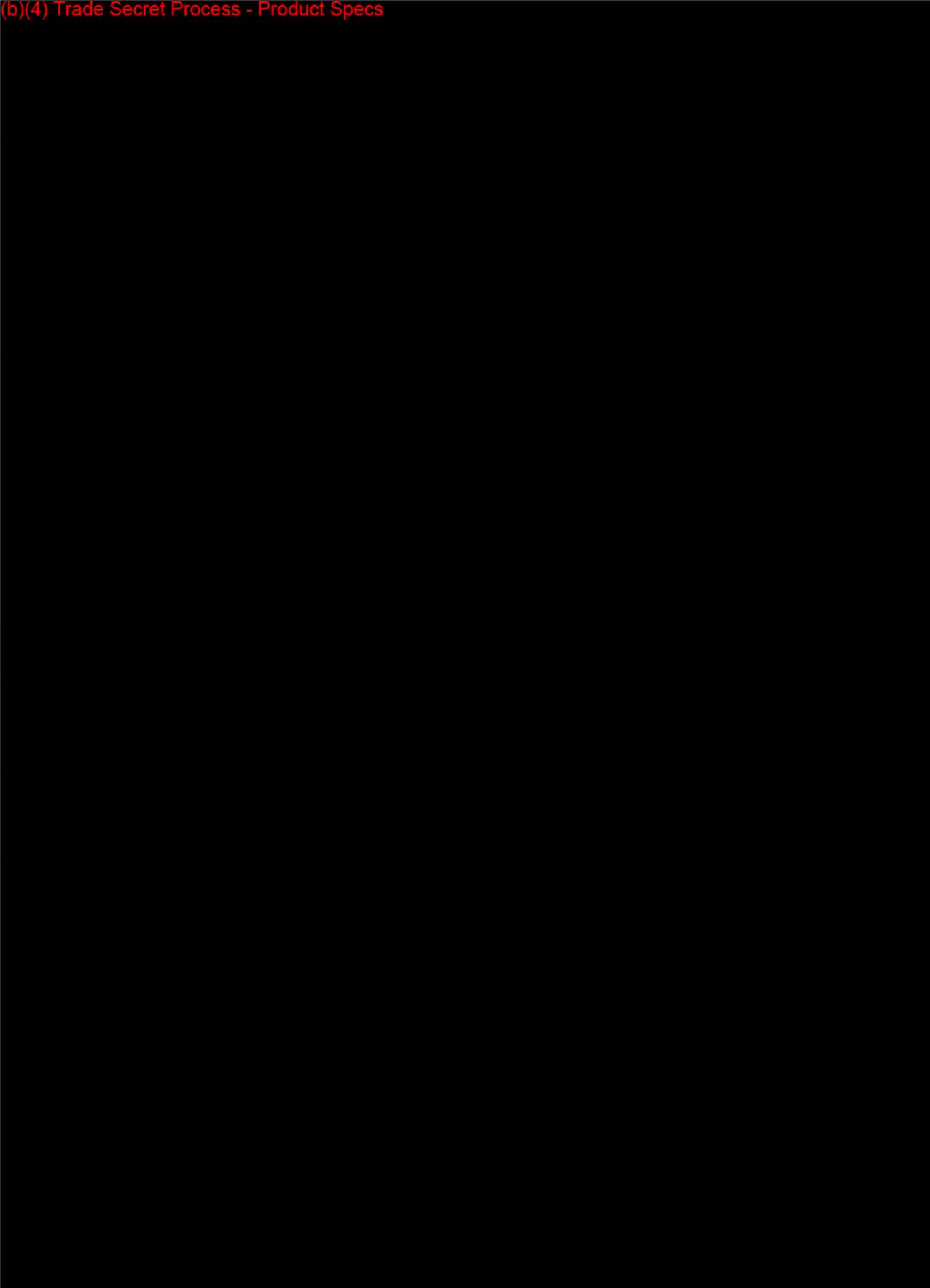
The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. The Light Fiber is provided sterile and is for single use only. It comes with a male tuohy borst adapter, which allows the device to be secured

Path Assist Light Fiber

K111763

Entellus Medical

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

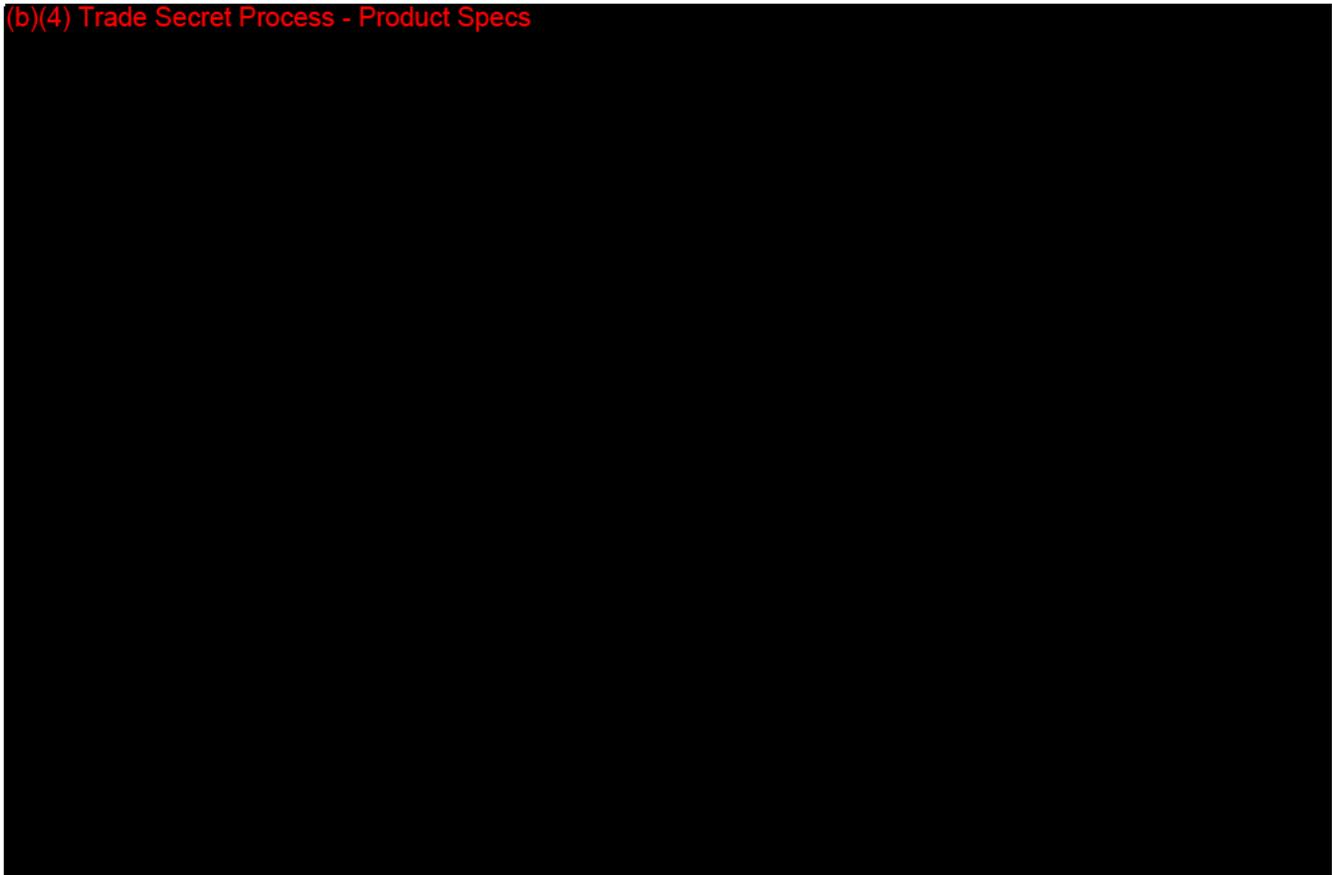


Path Assist Light Fiber

K111763

Entellus Medical

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



**Contraindications:**

None

**Technological Characteristics:**

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



**Principles of Operation (Section 13.5):**

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

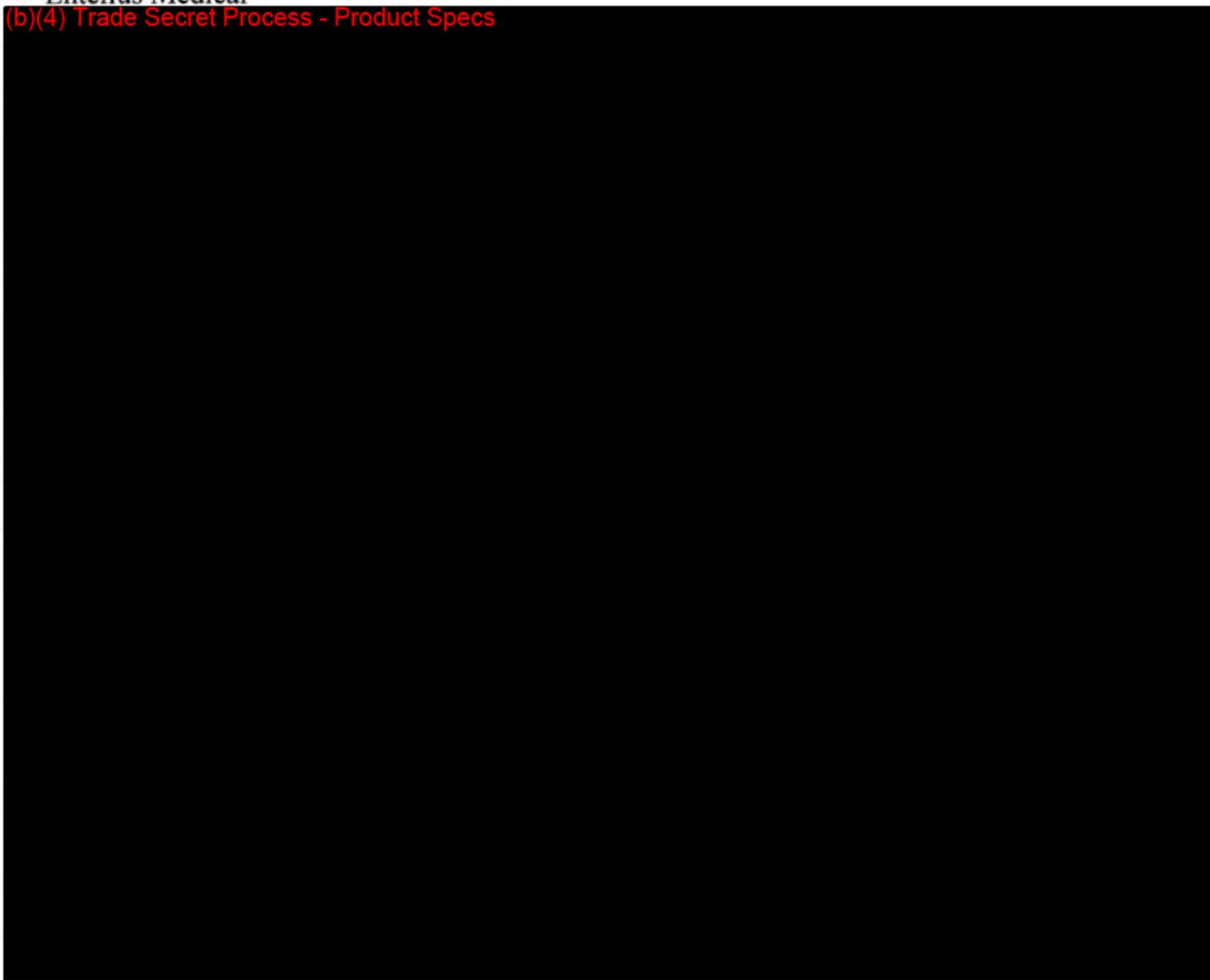


Path Assist Light Fiber

K111763

Entellus Medical

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



**PACKAGING (Section 13.6):**

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



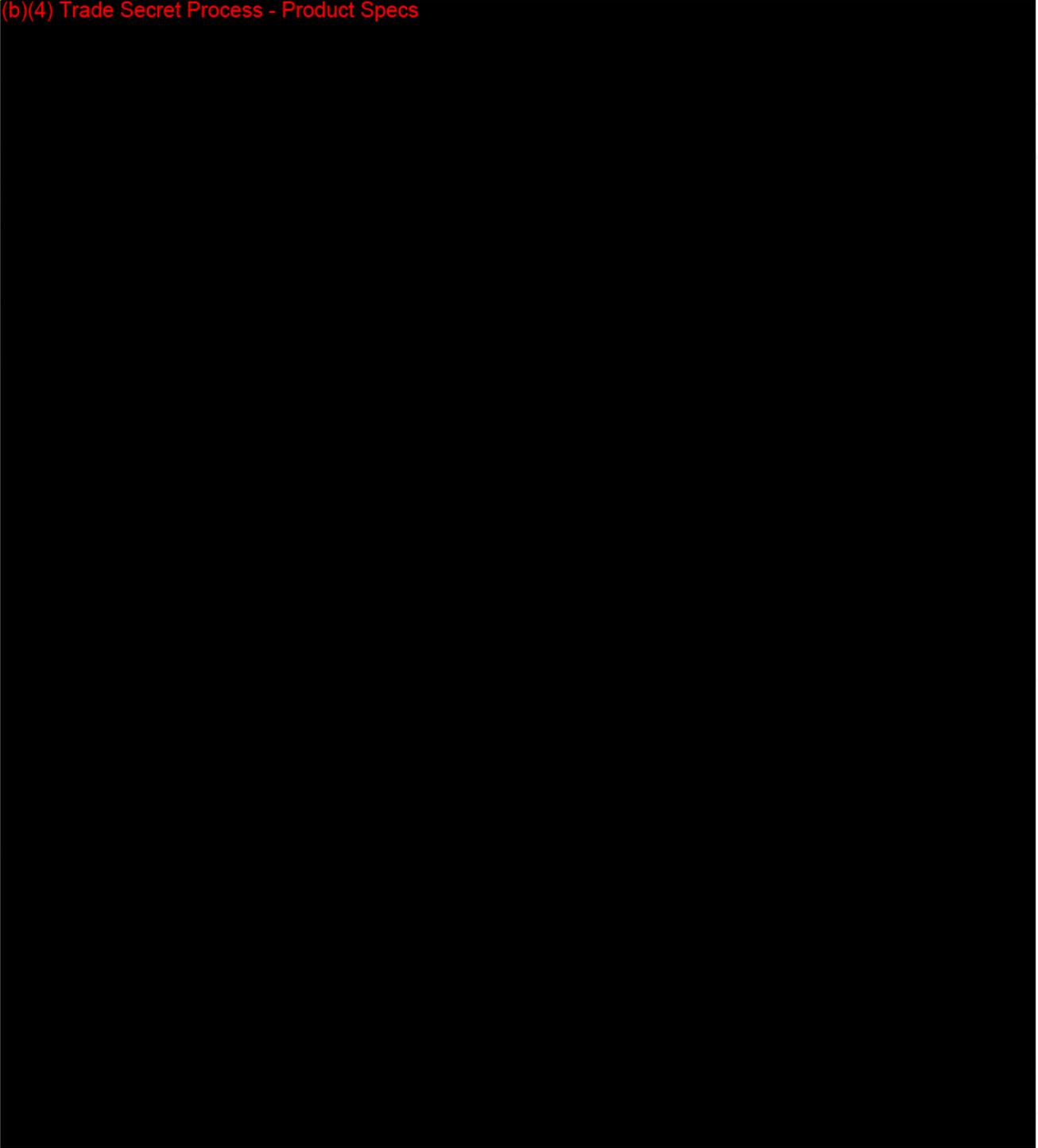
Path Assist Light Fiber

K111763

Entellus Medical

**ACCESSORIES PACKAGED WITH THE DEVICE ( Section 13.7):**

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

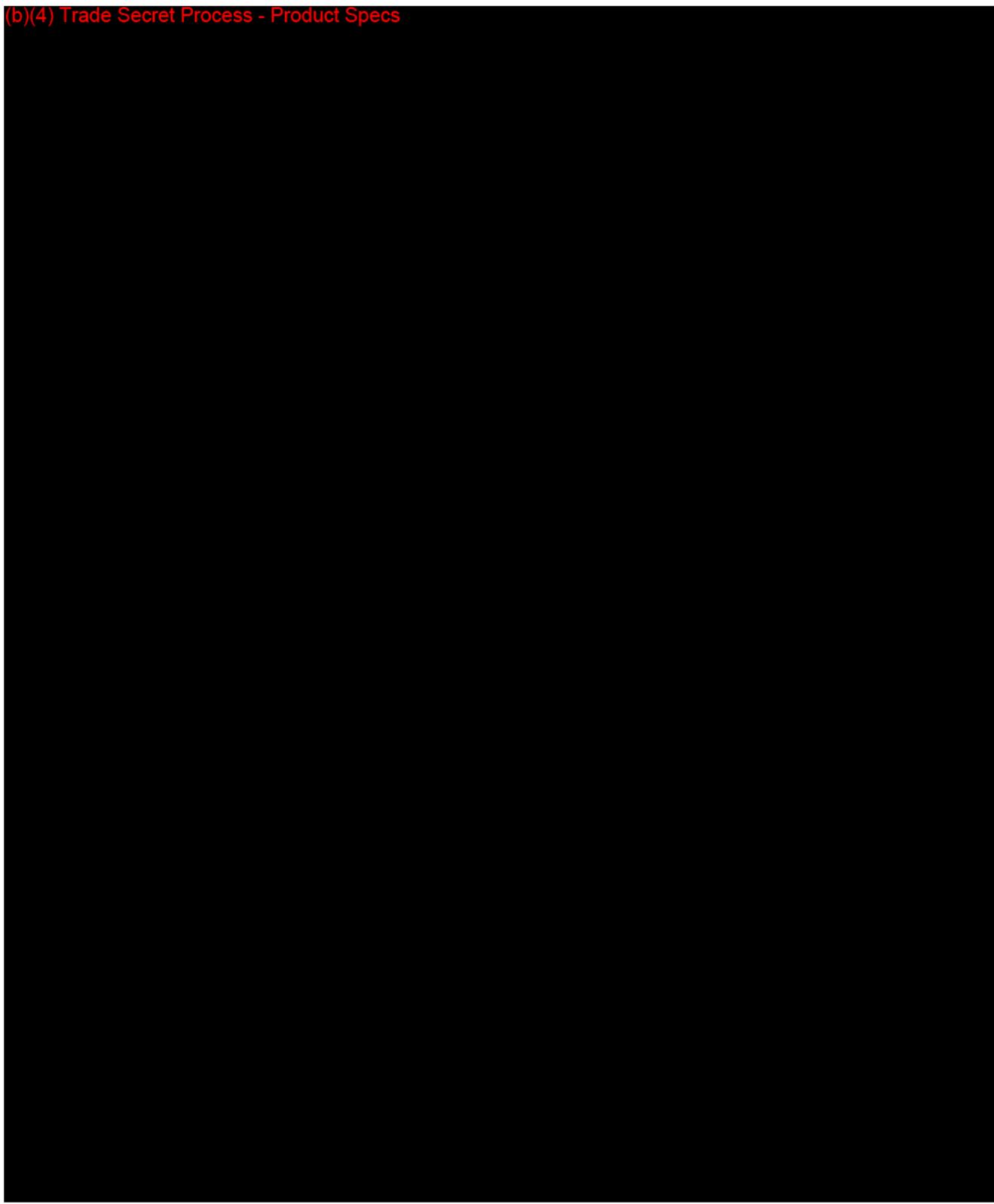


Path Assist Light Fiber

K111763

Entellus Medical

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

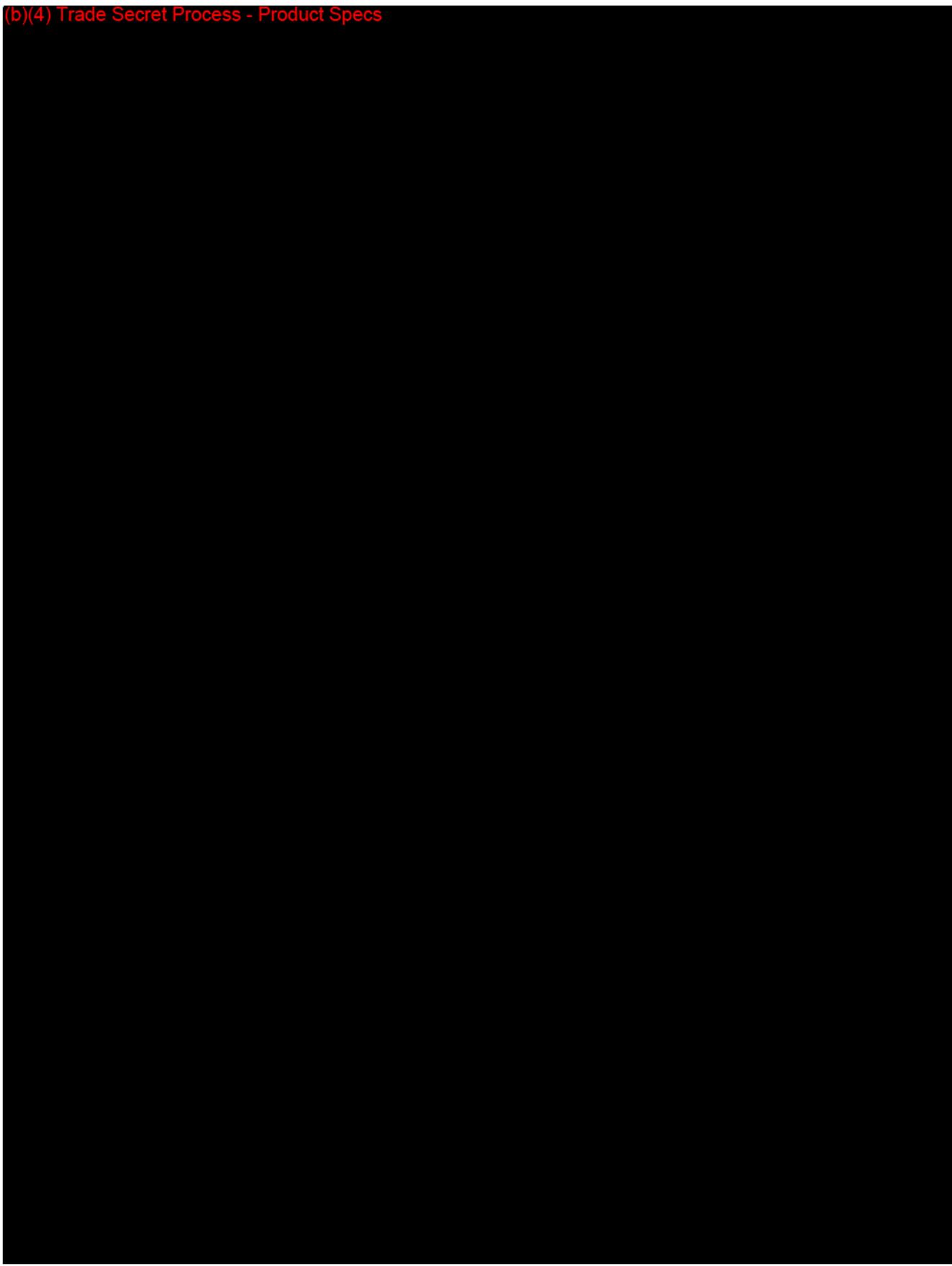


Path Assist Light Fiber

K111763

Entellus Medical

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

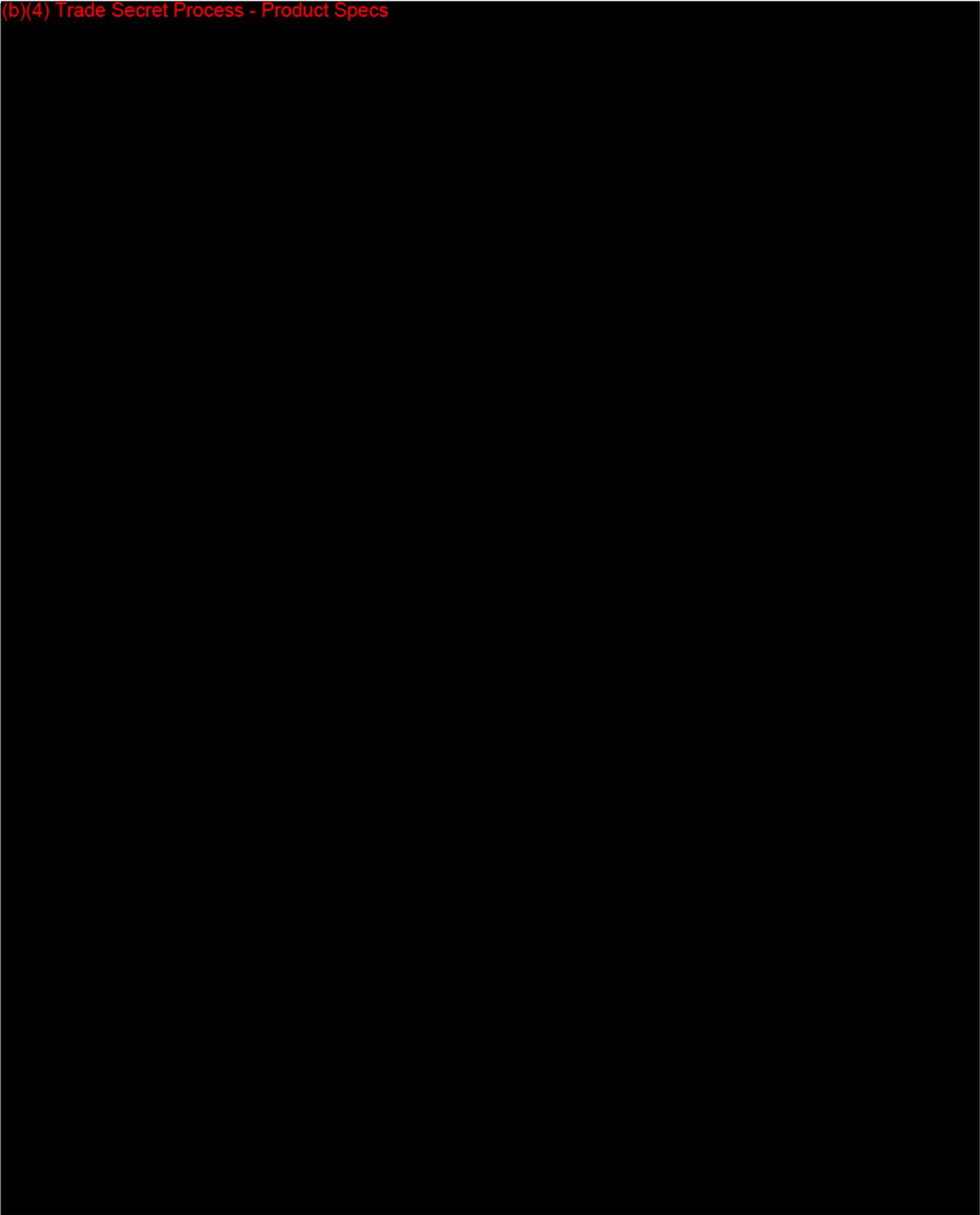


Path Assist Light Fiber

K111763

Entellus Medical

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

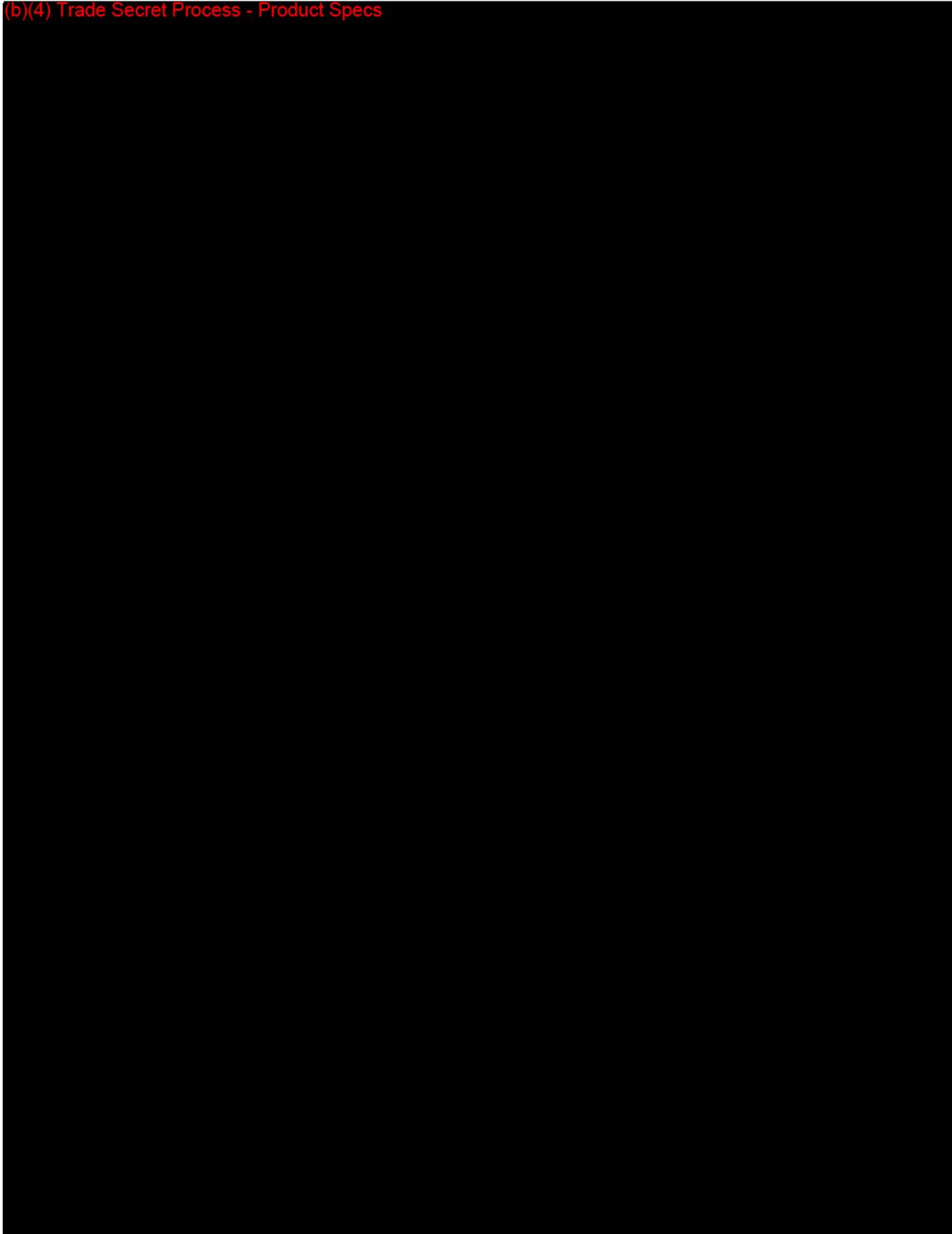


Path Assist Light Fiber

K111763

Entellus Medical

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



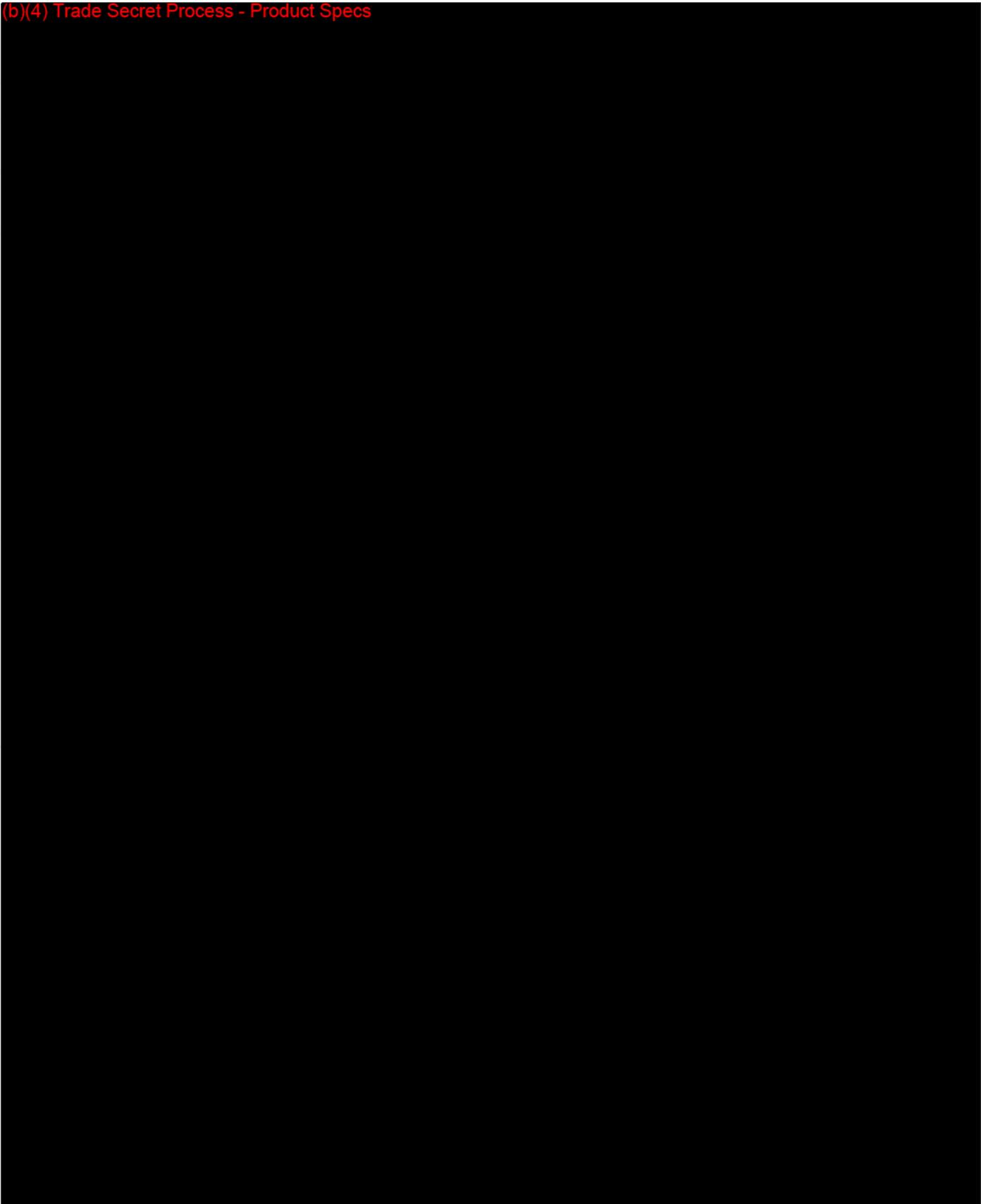
Path Assist Light Fiber

K111763

Entellus Medical

**Test Results:**

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

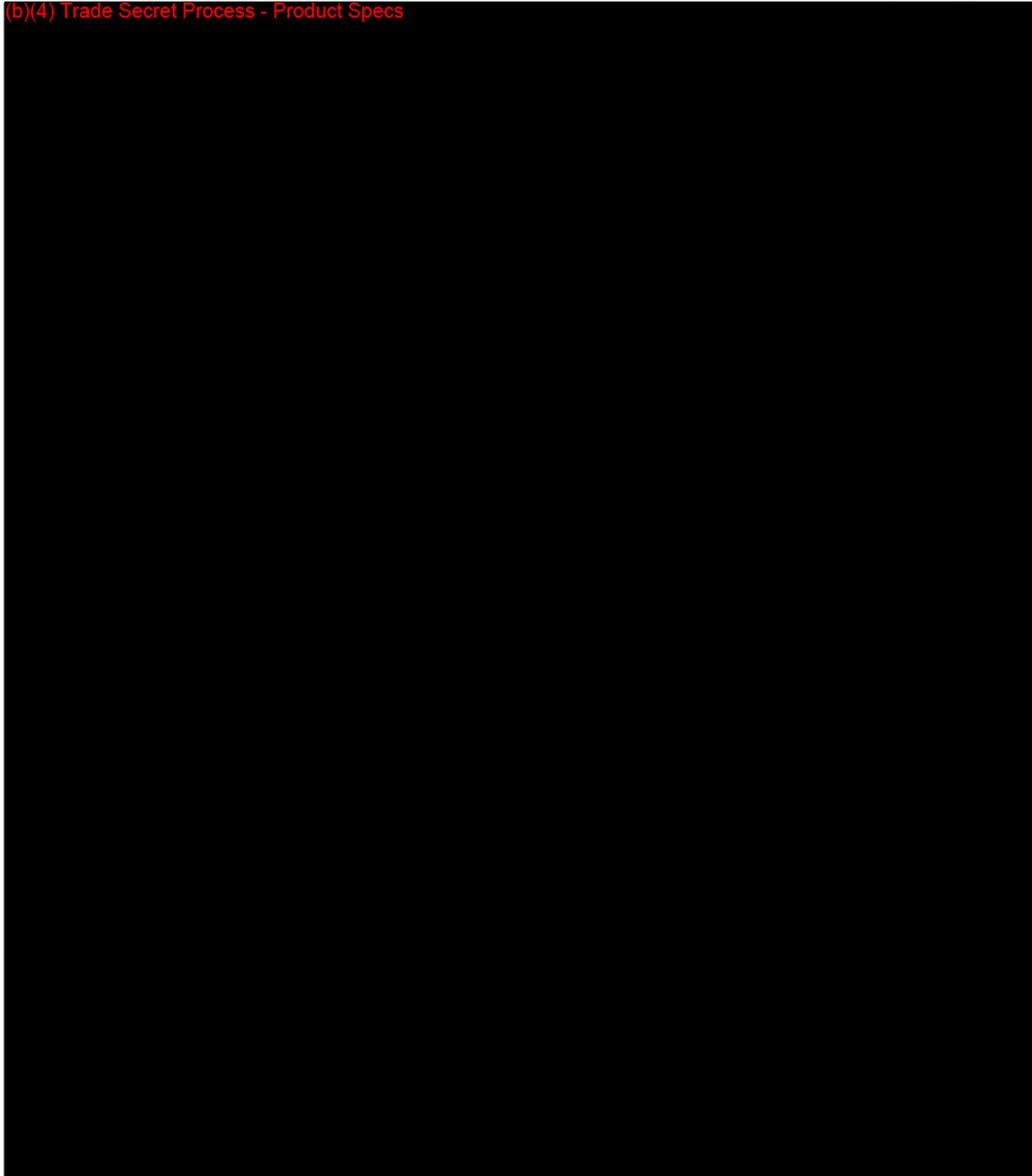


Path Assist Light Fiber

K111763

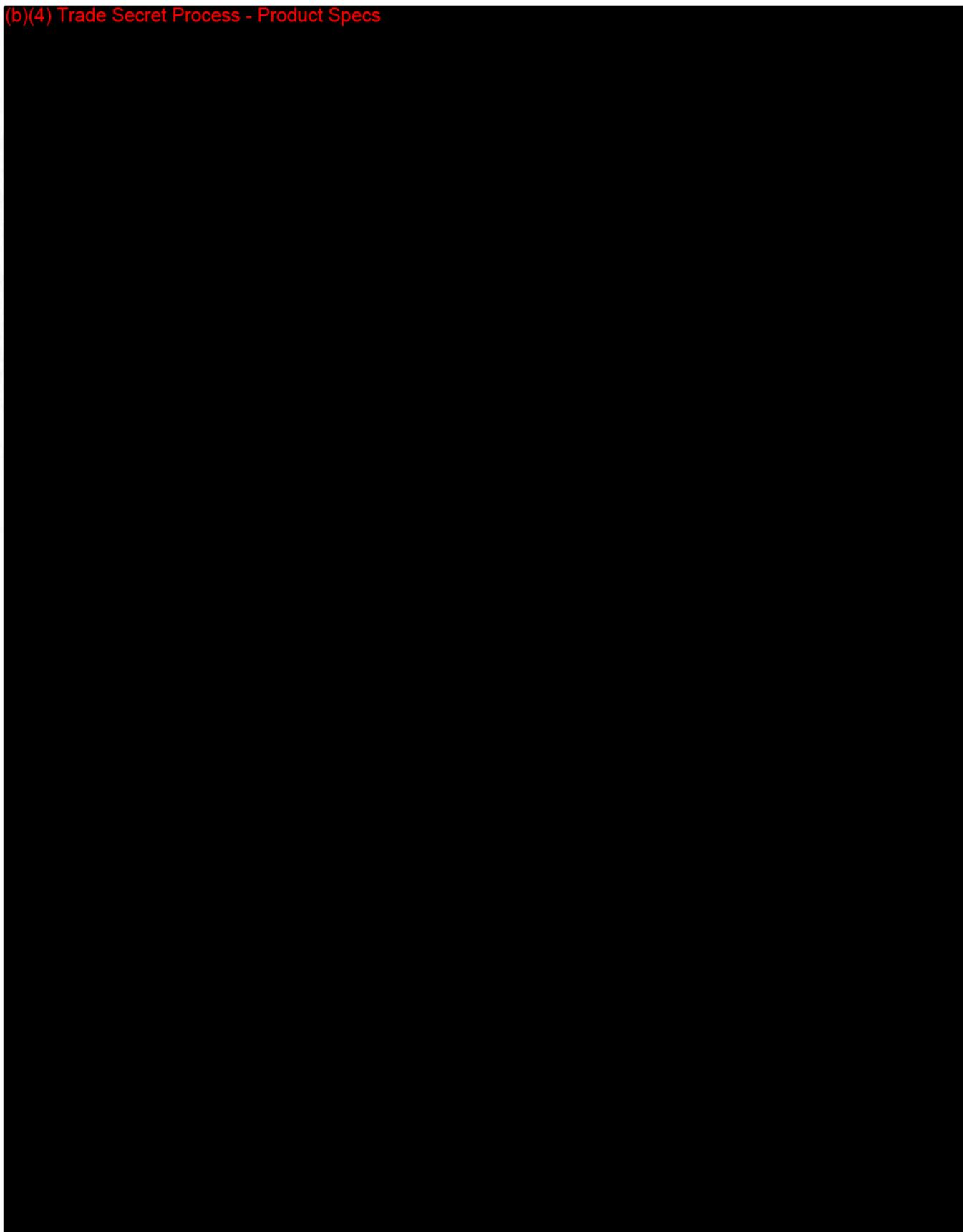
Entellus Medical

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



Path Assist Light Fiber  
K111763  
Entellus Medical

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

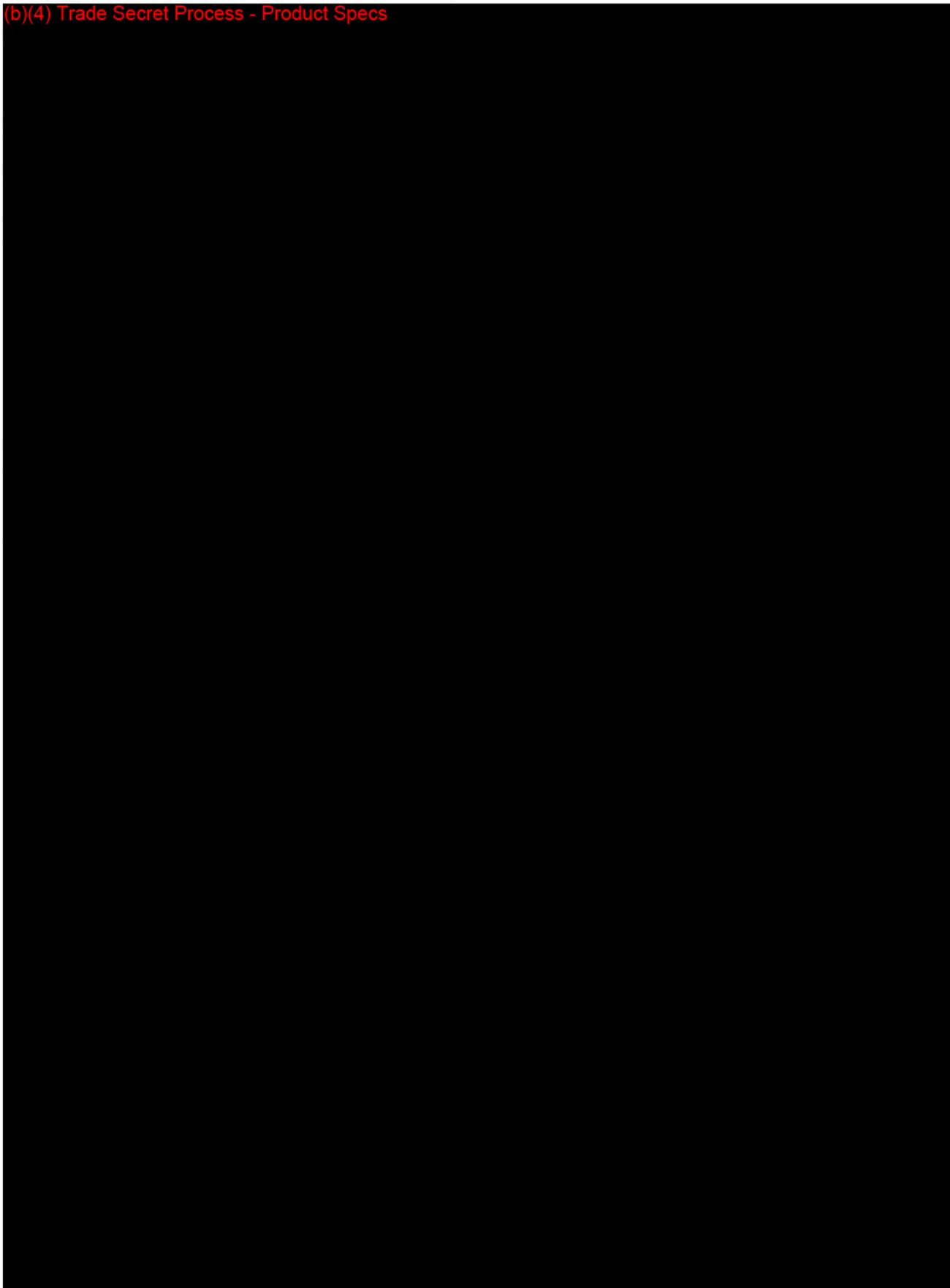


Path Assist Light Fiber

K111763

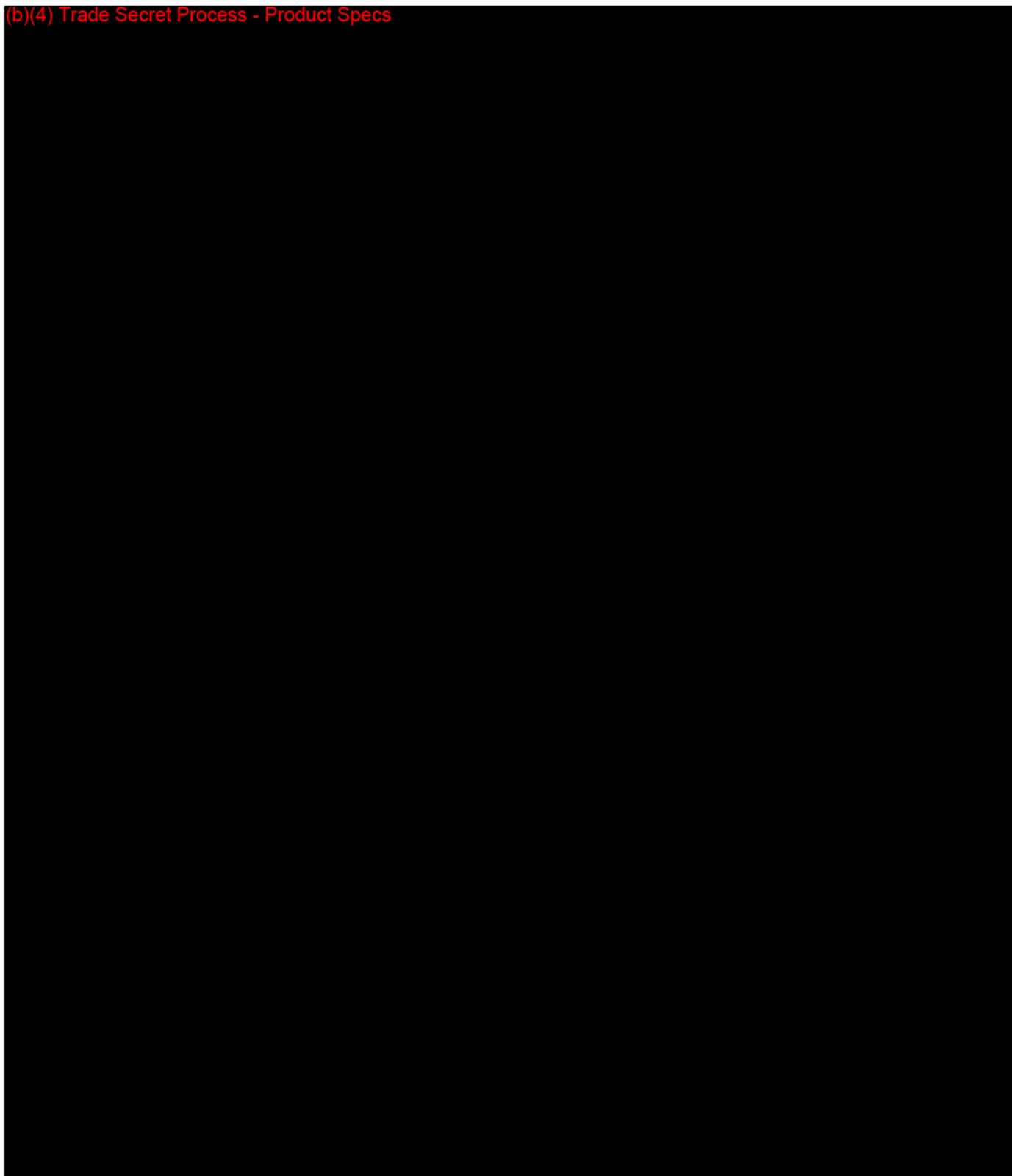
Entellus Medical

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



Path Assist Light Fiber  
K111763  
Entellus Medical

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



Path Assist Light Fiber

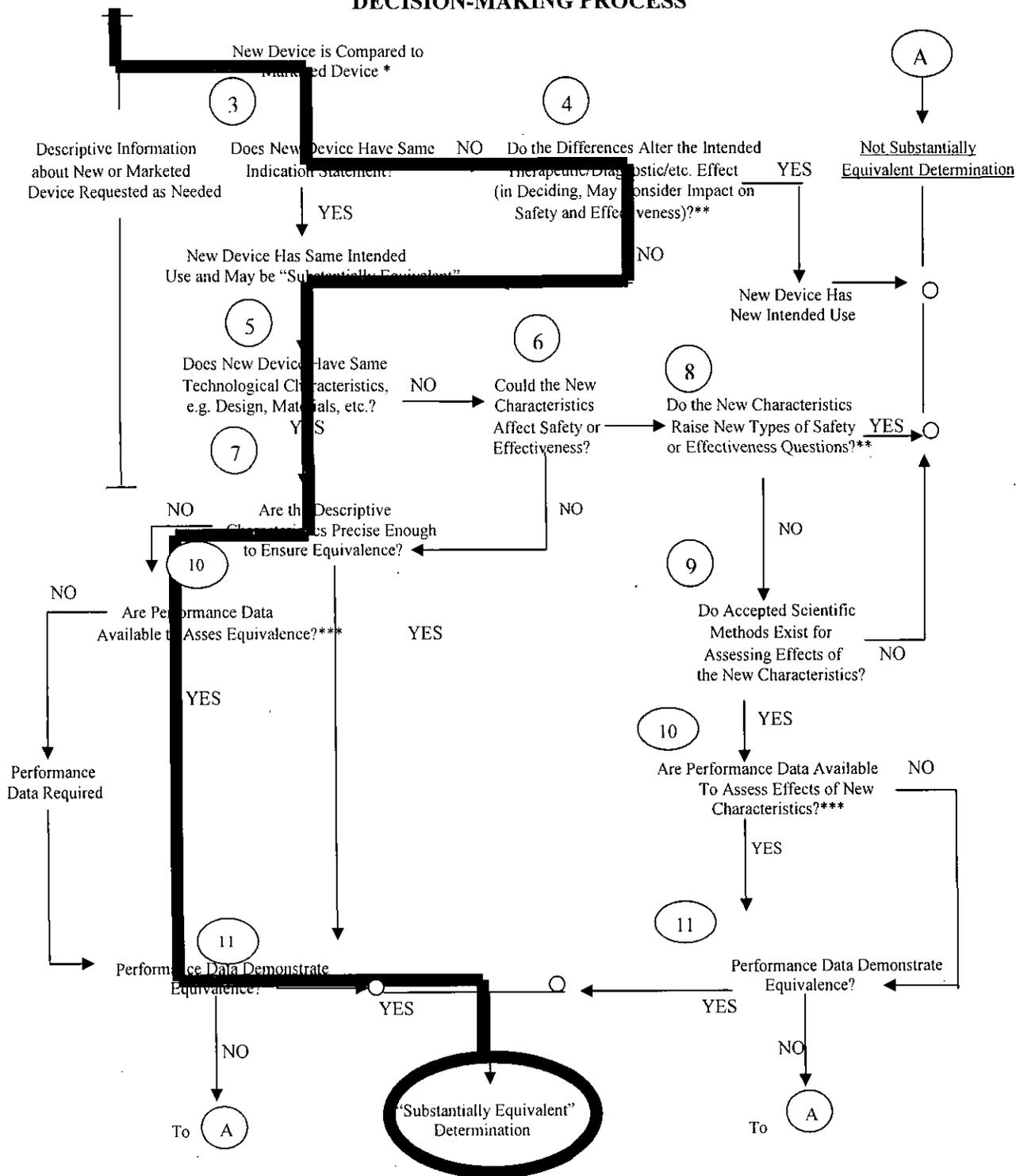
K111763

Entellus Medical

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



## 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.

EH / DONE

K111763 / S1



August 11, 2011

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – W066-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

FDA CDRH DMC  
AUG 12 2011  
Received

Re: K111763 – Additional Information  
Response to FDA Deficiency Letter of August 10, 2011 (sent via email)

K18

Dear Sir or Madam,

This Amendment to the above 510(k) Premarket Notification, submitted in duplicate, responds to the deficiencies identified in the FDA letter of August 10, 2011. We believe the enclosed response to FDA's letter addresses all of the questions identified by FDA.

To save FDA resources and facilitate the review, one paper copy and one electronic copy (eCopy) of this submission is provided. The eCopy follows the formatting requirements as per FDA's web instructions and it is an exact duplicate of the paper copy.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law in accordance with 21 CFR Part 20.

Thank you for your consideration of the information provided in this response to FDA's deficiency letter. If you have any questions or need any additional information during your review, please contact me by telephone at 763-463-7066 or 651-398-4341, or by email at [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com).

Sincerely,

A handwritten signature in cursive script that reads "Karen E. Peterson".

Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
Entellus Medical  
Office: 763-463-7066  
Cell: 651-398-4341  
Email: [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)



August 11, 2011

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – W066-G609  
10903 New Hampshire Avenue  
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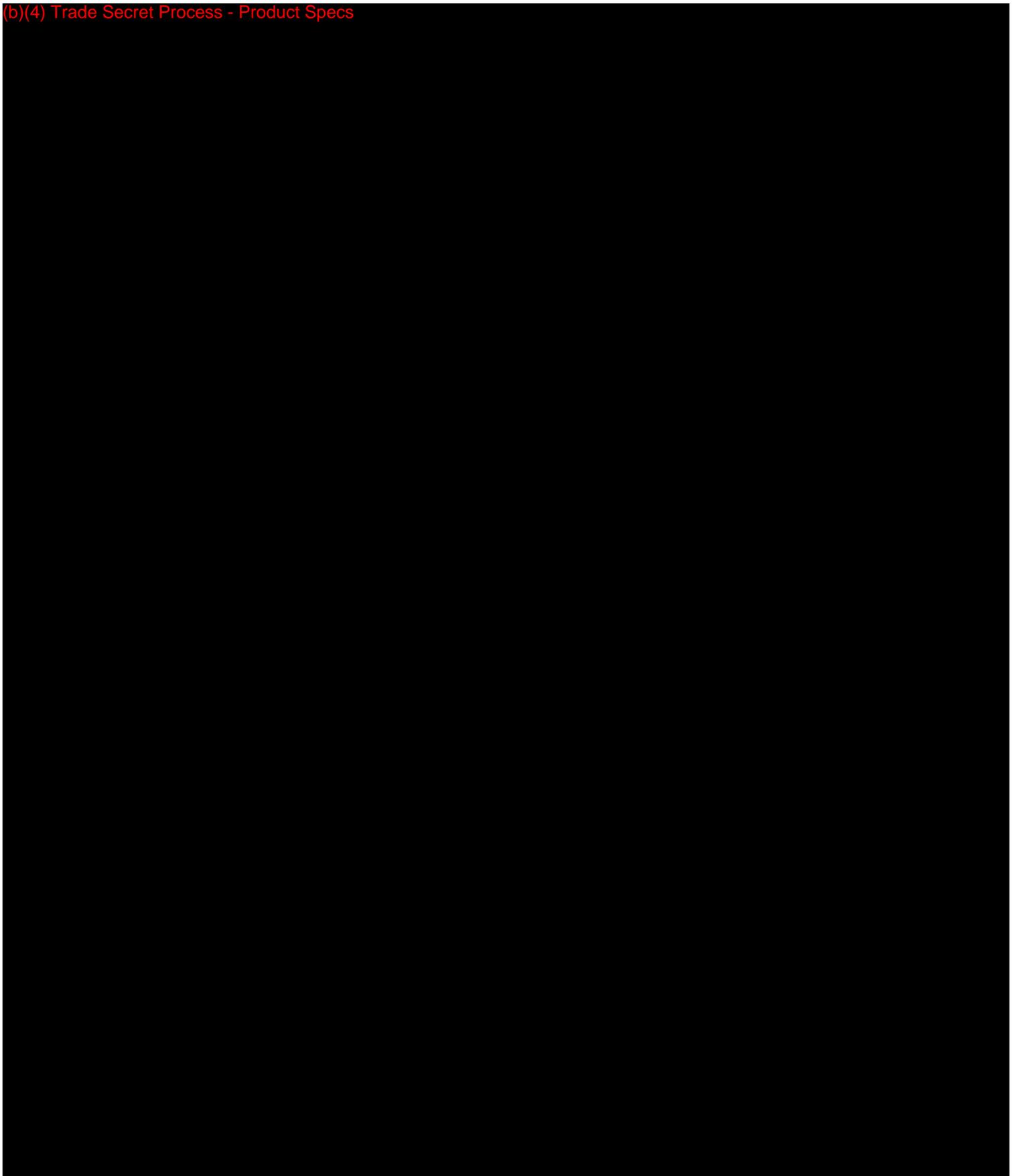
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Sincerely,

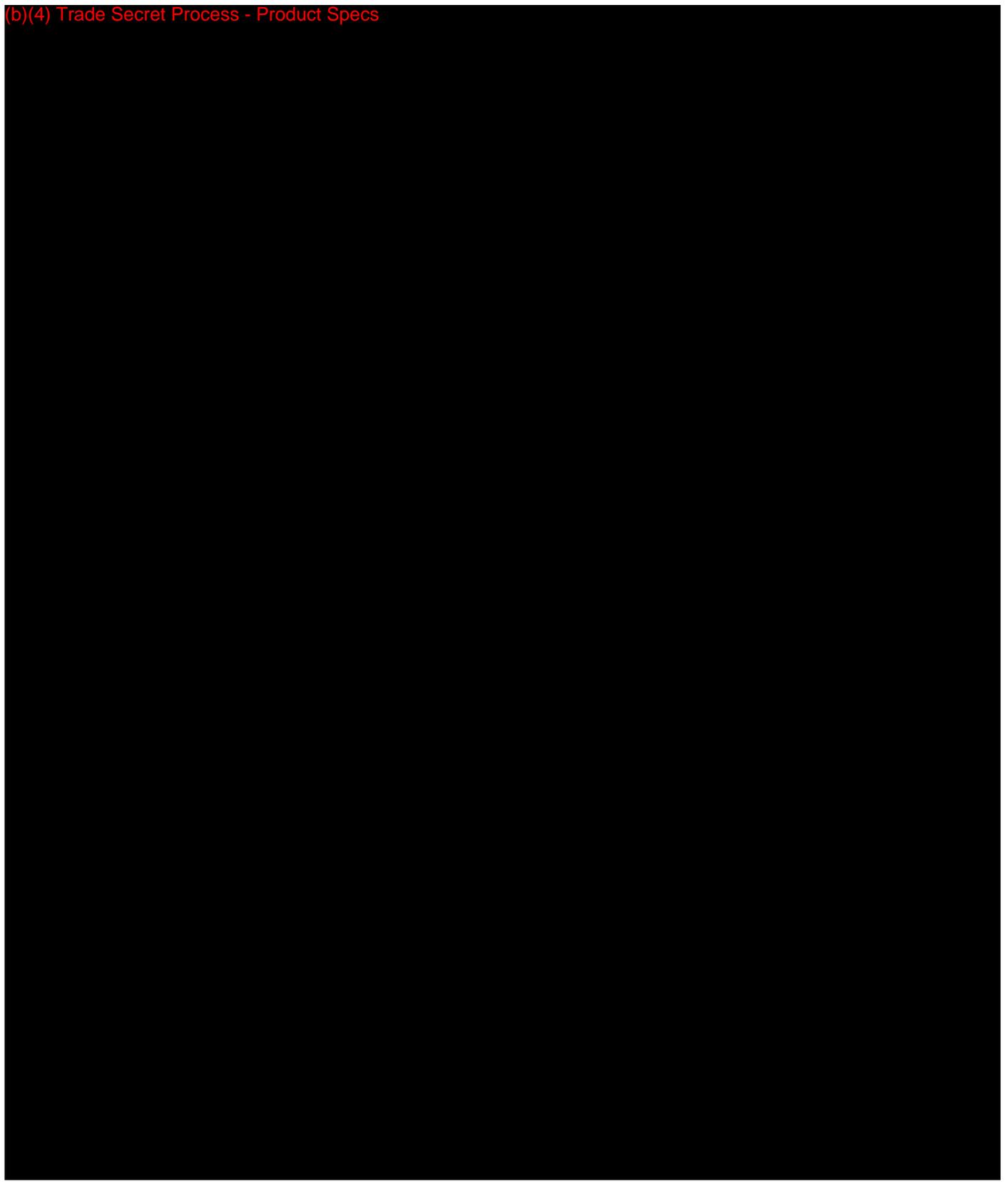
A handwritten signature in blue ink that reads "Karen E. Peterson".

Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
Entellus Medical  
Office: 763-463-7066  
Cell: 651-398-4341  
Email: [kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)

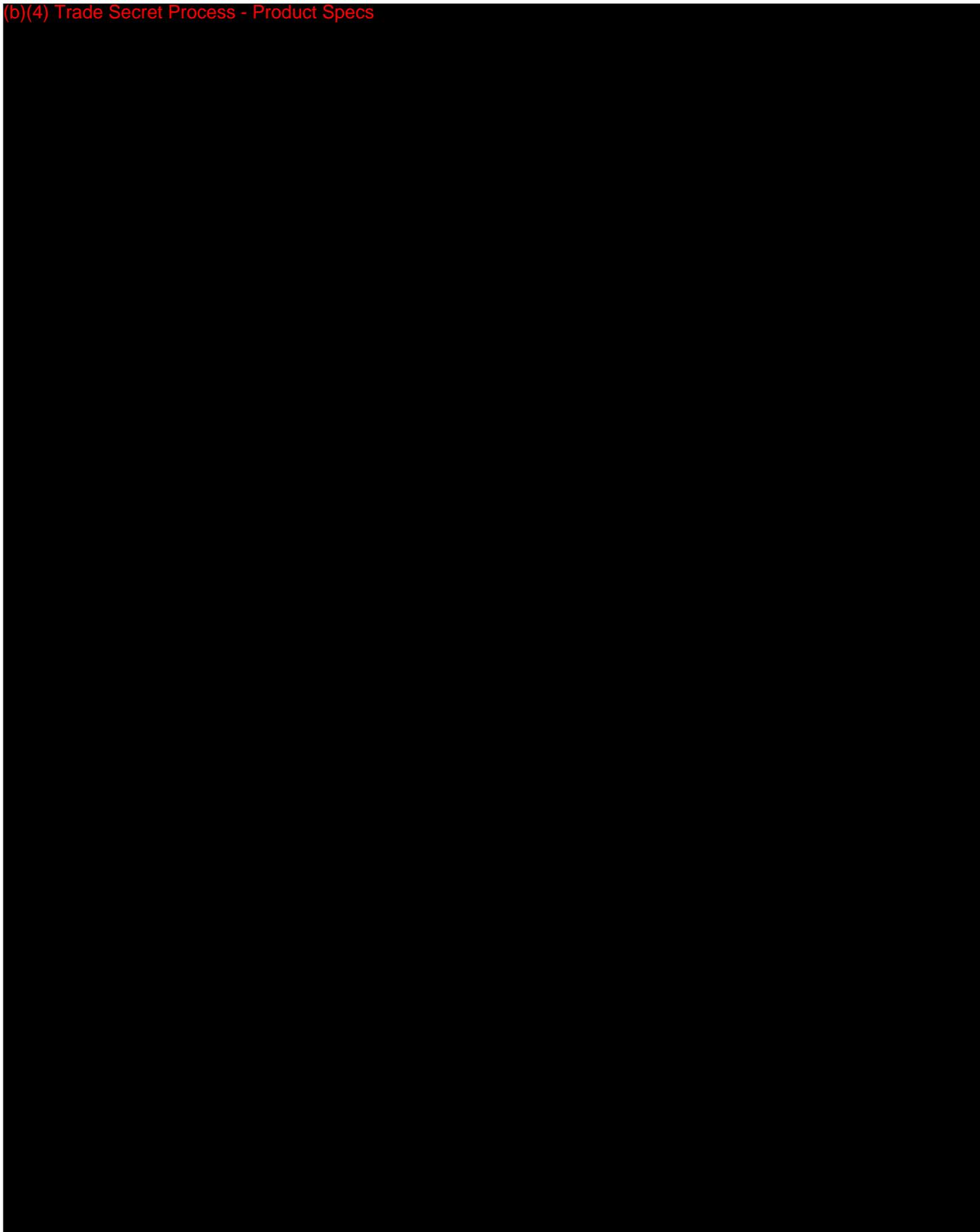
(b)(4) Trade Secret Process - Product Specs



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



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



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

