K110739

Entellus Medical

JUN 14 2011

510(k) Summary

Date Prepared:	June 13, 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
Device Information:	
Trade Name:	Entellus Medical Sinus Guidewire
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 Devices:
NeoMetrics Selectiva™ SB Guidewire [K033321, K013024]
Relieva Vigor™ Sinus Guidewire

Device Description:
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a polymer coating.

Indication for Use
To provide a means to access the frontal, sphenoid and maxillary sinuses, for diagnostic and therapeutic procedures in adults aged 18 and over.

Contraindications:
None

Technological Characteristics:
The device has the same technological characteristics (i.e., design, function, materials, biocompatibility, packaging and sterilization) as the predicate device [K033321, K013024]. The device has the same technological characteristics (i.e., design, function, principle of operation, and biocompatibility) as the predicate device (Relieva Vigor Sinus Guidewire). The subject and

predicate devices are all sterilized using Ethylene Oxide (EtO), validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of 10^{-6}. All devices 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 is the same as the predicate device (Relieva Vigor Sinus Guidewire). The technological characteristics of the subject device are the same as the predicate devices, [K033321, K013024] and/or Relieva Vigor Sinus Guidewire, including: design, function, principle of operation, materials, biocompatibility, packaging and sterilization.

Performance Data:
Performance testing of the Entellus Medical Sinus Guidewire consisted of design verification testing and a cadaver study. Design verification testing included simulated use and compatibility testing. A cadaver study was conducted to support the utility of this device in the sinus spaces. Biocompatibility, sterilization, packaging, shelf life 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

JUN 14 2011

Entellus Medical, Inc.
c/o Karen E. Peterson
Vice President, Clinical, Regulatory and Quality
705 Wedgwood Court North
Maple Grove, MN 55311 USA

Re: K110739
Trade/Device Name: Entellus Medical Sinus Guidewire
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose and Throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: March 16, 2011
Received: March 17, 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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

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

Indications for Use Statement

510(k) Number (if known): K110739

Device Name: Entellus Medical Sinus Guidewire

Indications for Use

To provide a means to access the frontal, sphenoid and maxillary sinuses, for diagnostic and therapeutic procedures 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 _____

Susan Rudy CRNP

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

510(k) Number K110739

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

JUN 14 2011

Entellus Medical, Inc.
c/o Karen E. Peterson
Vice President, Clinical, Regulatory and Quality
705 Wedgwood Court North
Maple Grove, MN 55311 USA

Re: K110739
Trade/Device Name: Entellus Medical Sinus Guidewire
Regulation Number: 21 CFR 874.4420
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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
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Indications for Use Statement

510(k) Number (if known): K110739

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Indications for Use

To provide a means to access the frontal, sphenoid and maxillary sinuses, for diagnostic and therapeutic procedures 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_____

Susan Rudy CRNP

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

510(k) Number K110739

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 20993-0002

March 17, 2011

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

510k Number: K110739
Received: 3/17/2011
Product: ENTELLUS MEDICAL SINUS GUIDEWI

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

CONFIDENTIAL

K110739

4. Cover Letter

March 16, 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 Entellus Medical Sinus Guidewire

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 Entellus Medical Sinus Guidewire. The Sinus Guidewire is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

(b)(4) Confidential and Proprietary Information

[redacted]

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.

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

(b)(4) Confidential and Proprietary Information

[redacted]

Common / Usual Name	Sinus Guidewire
Trade Name	Entellus Medical Sinus Guidewire
Classification Regulation	21CFR 878.4800
Classification Name	Manual Surgical Instrument for General Use
Classification Panel	General and Plastic Surgery
Class	Class I
Product Code	KAM
Model Number	PTW
Identification of Predicate Devices	NeoMetrics Selectiva™ SB Guidewire [K033321, K013024] Relieva Vigor™ Sinus Guidewire [K043445]

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?		√

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.

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 the Company 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.

Sincerely,

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

Traditional 510(k) Premarket Notification

Entellus Medical Sinus Guidewire

Date: March 16, 2011

Submitted by:

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.

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Attachments

Attachment 1	Medical Device User Fee Cover Sheet (Form FDA 3601)
Attachment 2	Indications for Use Statement
Attachment 3	510(k) Summary
Attachment 4	Standards Data Report Forms for 510(k)s – FDA 3654
(b)(4) Confidential and Proprietary Information	
Attachment 6	Information & IFU on Predicate Device: NeoMetrics Selectiva SB Guidewire [K033321, K013024]
Attachment 7	Information & IFU on Predicate Device: Acclarent Relieva Vigor Guidewire [K043445]
Attachment 8	Packaging Label
Attachment 9	Instructions for Use (IFU)
Attachment 10	Sinus Guidewire Simulated Use and Device Compatibility Design Verification Protocol and Report
Attachment 11	DHF-1311Sinus Guidewire Fluoroscopic Compatibility Report
(b)(4) Confidential and Proprietary Information	

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	User Fee Payment ID Number	FDA Submission Document Number (if known)
March 16, 2011	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other
☐ Supplement	☐ Supplement			*(describe submission):*
	☐ Report			
	☐ Report Amendment			

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

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

Request for Removal of Applicant Hold

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
- ☐ Conditional Approval
- ☐ Deemed Approved
- ☐ Deficient Final Report
- ☐ Deficient Progress Report
- ☐ Deficient Investigator Report
- ☐ Disapproval
- ☐ Request Extension of Time to Respond to FDA
- ☐ Request Meeting
- ☐ Request Hearing

Manufacturer

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	**DQX**	2	**KAM**	3		4	
5		6		7		8	

Summary of, or statement concerning, **safety and effectiveness information**

☒ 510 (k) summary attached

☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	**K033321, K013024**		**Selectiva™ SB Guidewire**		**NeoMetrics, Inc.**
2	**K043445**		**Relieva Vigor™ Sinus Guidewire**		**Acclarent, Inc.**
3					
4		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Common name: Sinus Guidewire

Classification name: Manual Surgical Instrument for General Use

	Trade or Proprietary or Model Name for This Device		**Model Number**
1	**Entellus Medical Sinus Guidewire**	1	**PTW**
2		2	

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
KAM

C.F.R. Section *(if applicable)*
21 CFR 878.4800

Classification Panel
General and Plastic Surgery

Device Class

☒ **Class I** ☐ **Class II**

☐ Class III ☐ Unclassified

Indications *(from labeling)*

To provide a means to access the sinus space for diagnostic and therapeutic procedures.

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

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

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[redacted]

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.

(b)(4) Confidential and Proprietary Information

8					
9					

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. Cover Letter

March 16, 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 Entellus Medical Sinus Guidewire

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 Entellus Medical Sinus Guidewire. The Sinus Guidewire is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

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[redacted]

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.

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

(b)(4) Confidential and Proprietary Information

[redacted]

Common / Usual Name	Sinus Guidewire
Trade Name	Entellus Medical Sinus Guidewire
Classification Regulation	21CFR 878.4800
Classification Name	Manual Surgical Instrument for General Use
Classification Panel	General and Plastic Surgery
Class	Class I
Product Code	KAM
Model Number	PTW
Identification of Predicate Devices	NeoMetrics Selectiva™ SB Guidewire [K033321, K013024] Relieva Vigor™ Sinus Guidewire [K043445]

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?		√

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.

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 the Company 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.

Sincerely,

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

5. 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

X 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)] Manual.	Section 4	
Table of Contents.	Section 1	
Truthful and Accurate Statement.	Section 8	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Sections 3,4	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Sections 3,4	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	Section 15	
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 6 & Attachment 2	
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)] Manual.	Section 14	
510(k) Summary or 510(k) Statement.	Section 7 & Attachment 3	
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 3,4, 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	

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

	Present	Inadequate or Missing
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

6. Indications for Use Statement

The Indications for Use Statement is in Attachment 2.

7. 510(k) Summary

The 510(k) Summary is in Attachment 3.

8. 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.

Karen E Peterson Date: 3-16-11

Karen E. Peterson
Vice President Clinical, Regulatory and Quality

9. Class III Summary and Certification

Not applicable. Device is a class I device.

10. Financial Certification

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

11. Declarations of Conformity

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:

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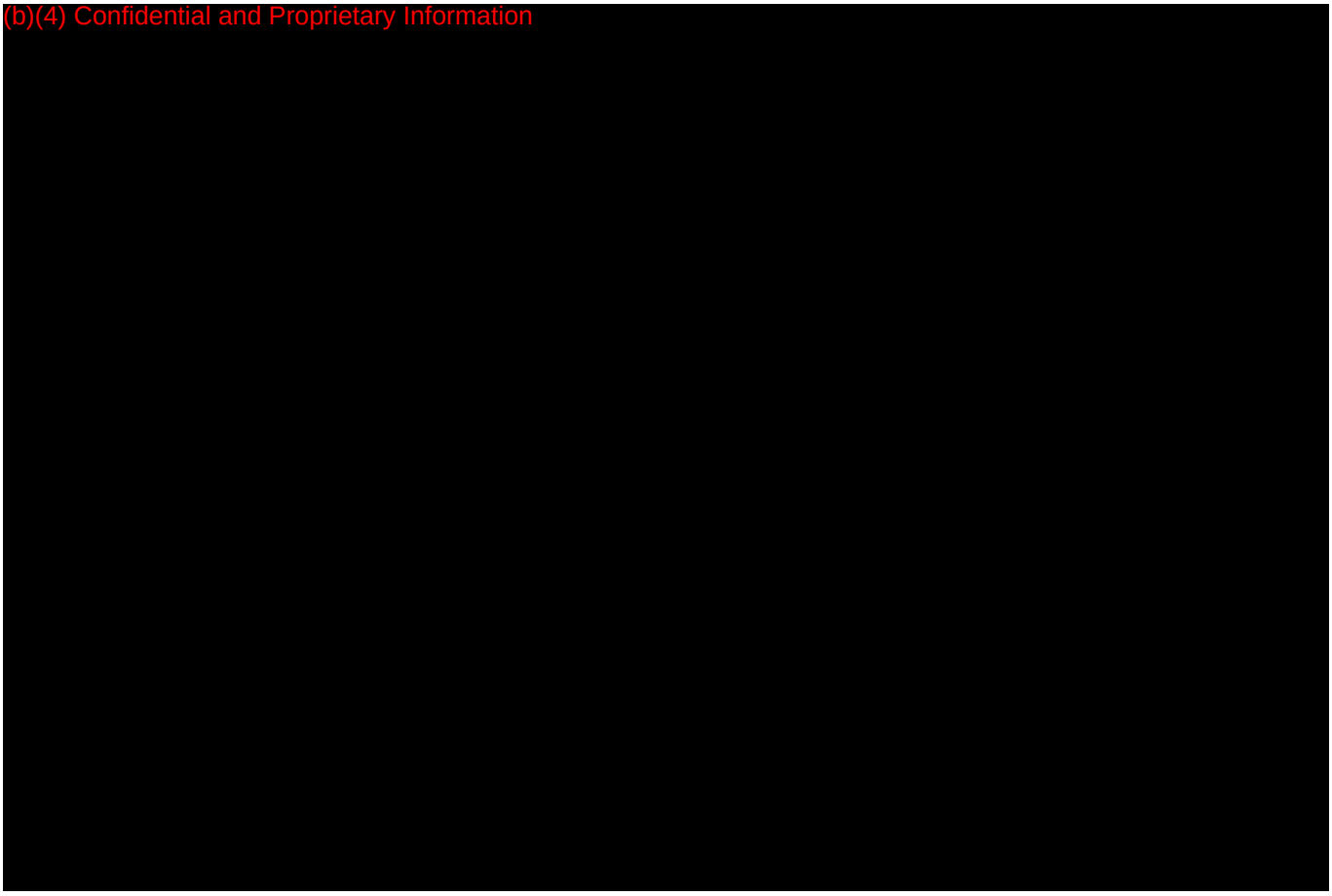

Standards Data Report Forms for 510(k)s – FDA 3654, for the standards listed above are provided in Attachment 4.

12. Executive Summary

Device Description
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a lubricious coating.

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

Indication for Use
To provide a means to access the sinus space for diagnostic and therapeutic procedures.

Substantial Equivalence

The Entellus Medical Sinus Guidewire (subject device) is substantially equivalent to the predicate devices: Selectiva SB Guidewire [K033321, K013024] and Relieva Vigor Sinus Guidewire [K043445].

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The intended use of the subject device is similar to the Selectiva SB Guidewire predicate and identical to the Relieva Vigor Sinus Guidewire predicate.

In summary, we believe that the Entellus Medical Sinus Guidewire described in this submission is substantially equivalent to the predicate devices.

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

Performance Specifications & Design Requirements

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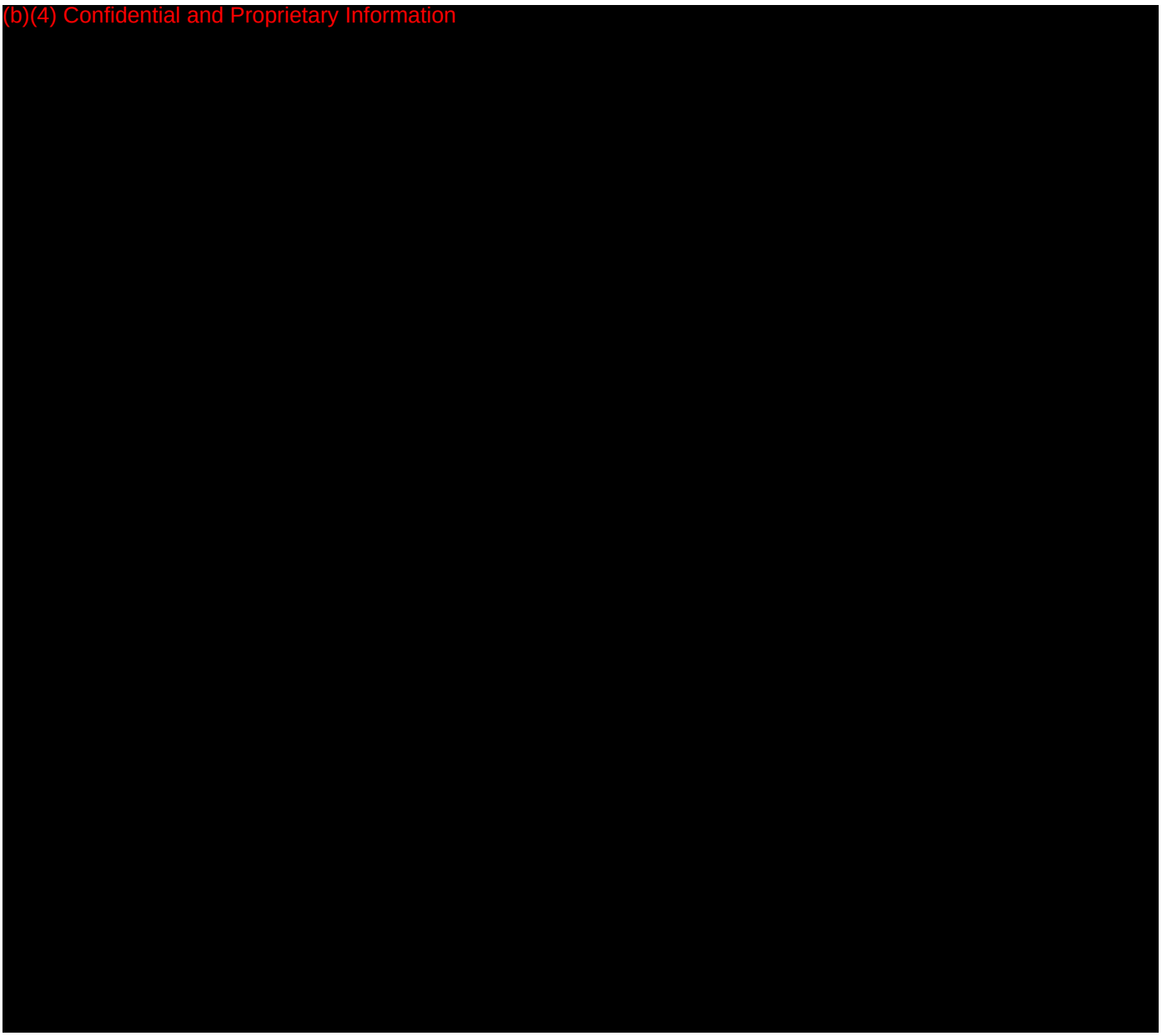
(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

15. Proposed Labeling

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

Packaging label: Attachment 8

Instructions for Use (IFU): Attachment 9.

Promotional literature and advertisements have not been developed.

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

18. Software

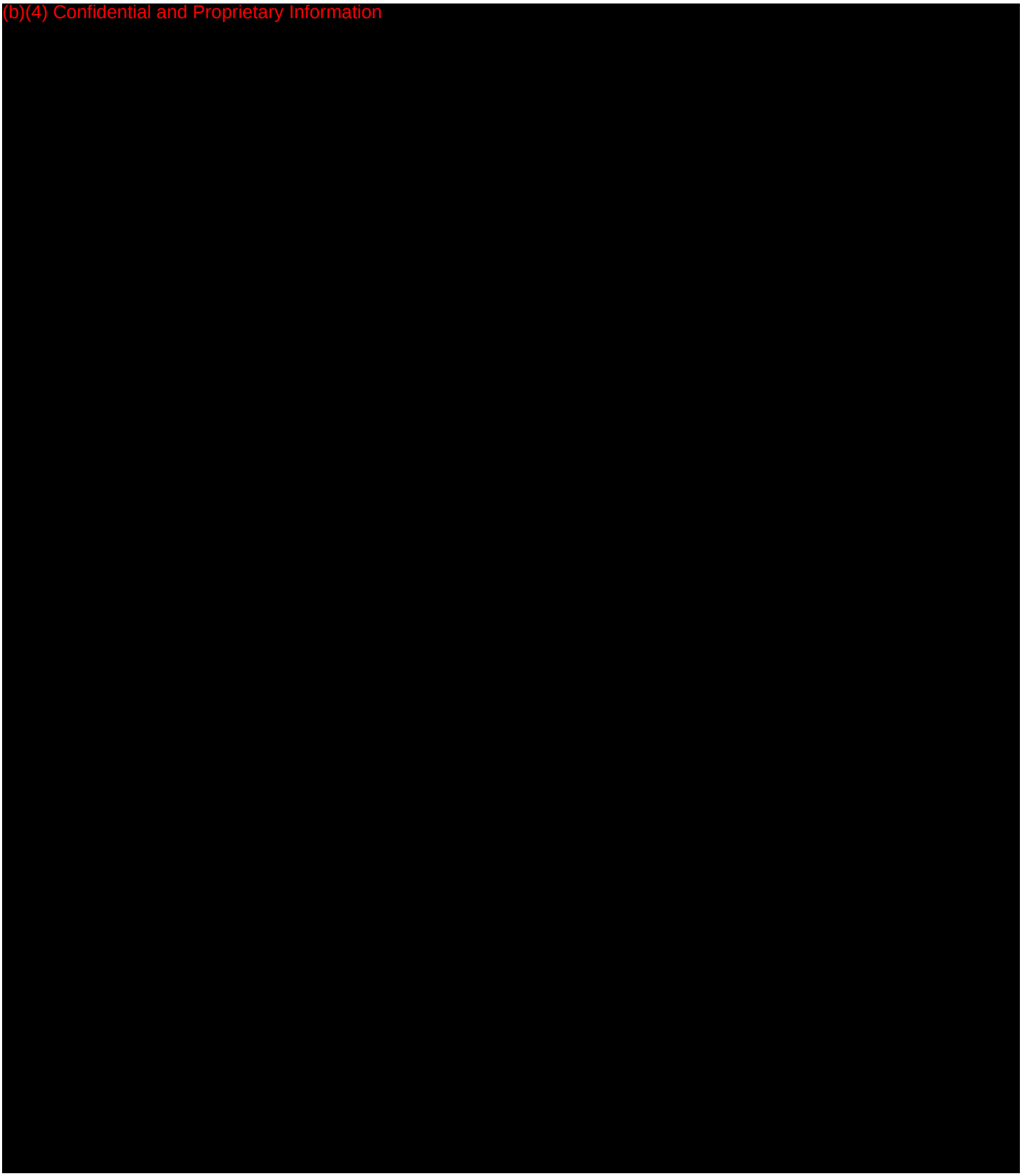
Not applicable. The device does not contain any software.

19. EMC and Electrical Safety

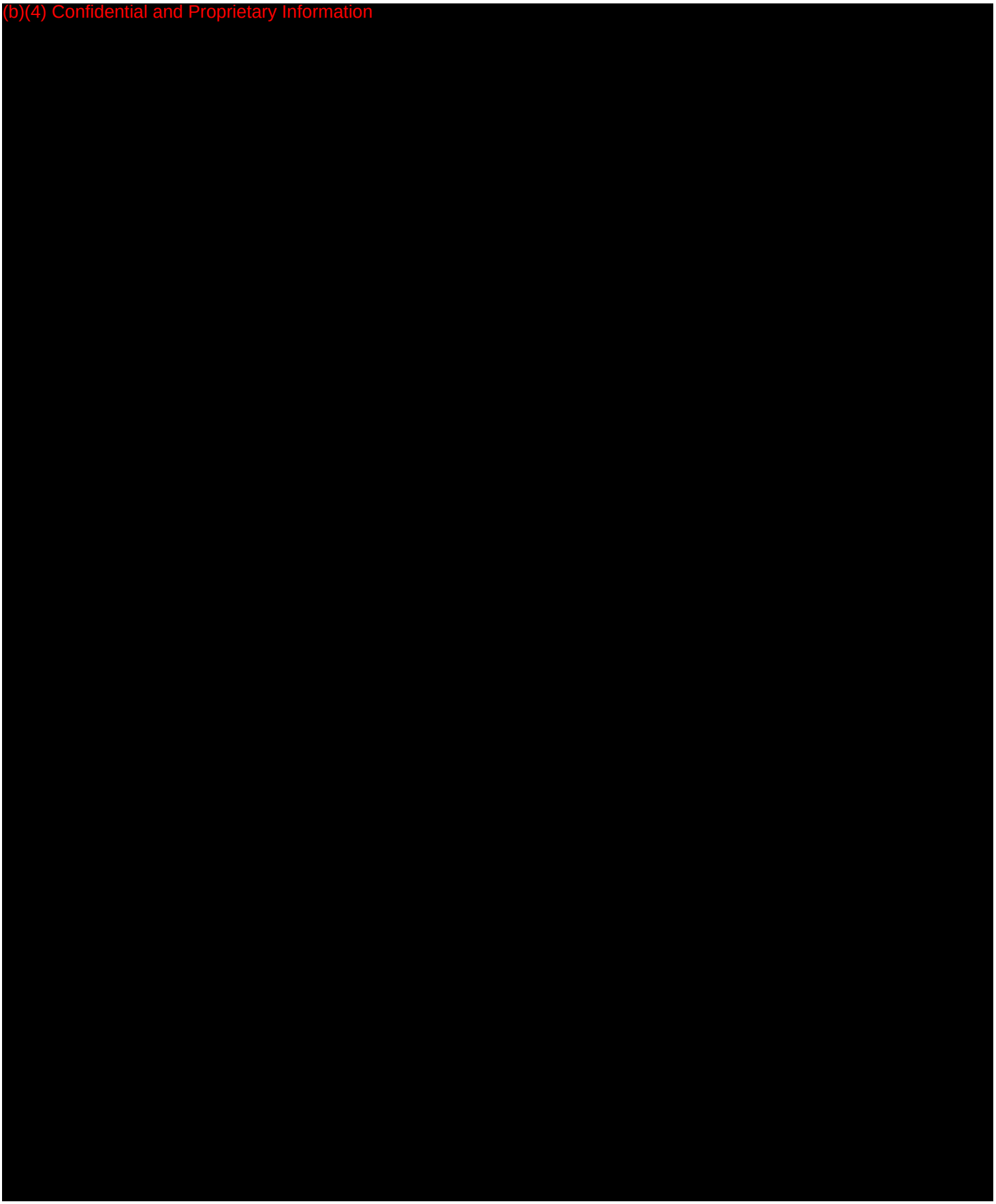
Not applicable. The device does not contain any electrical component nor will it be affected by any electromagnetic emission.

20. Performance Testing - Bench

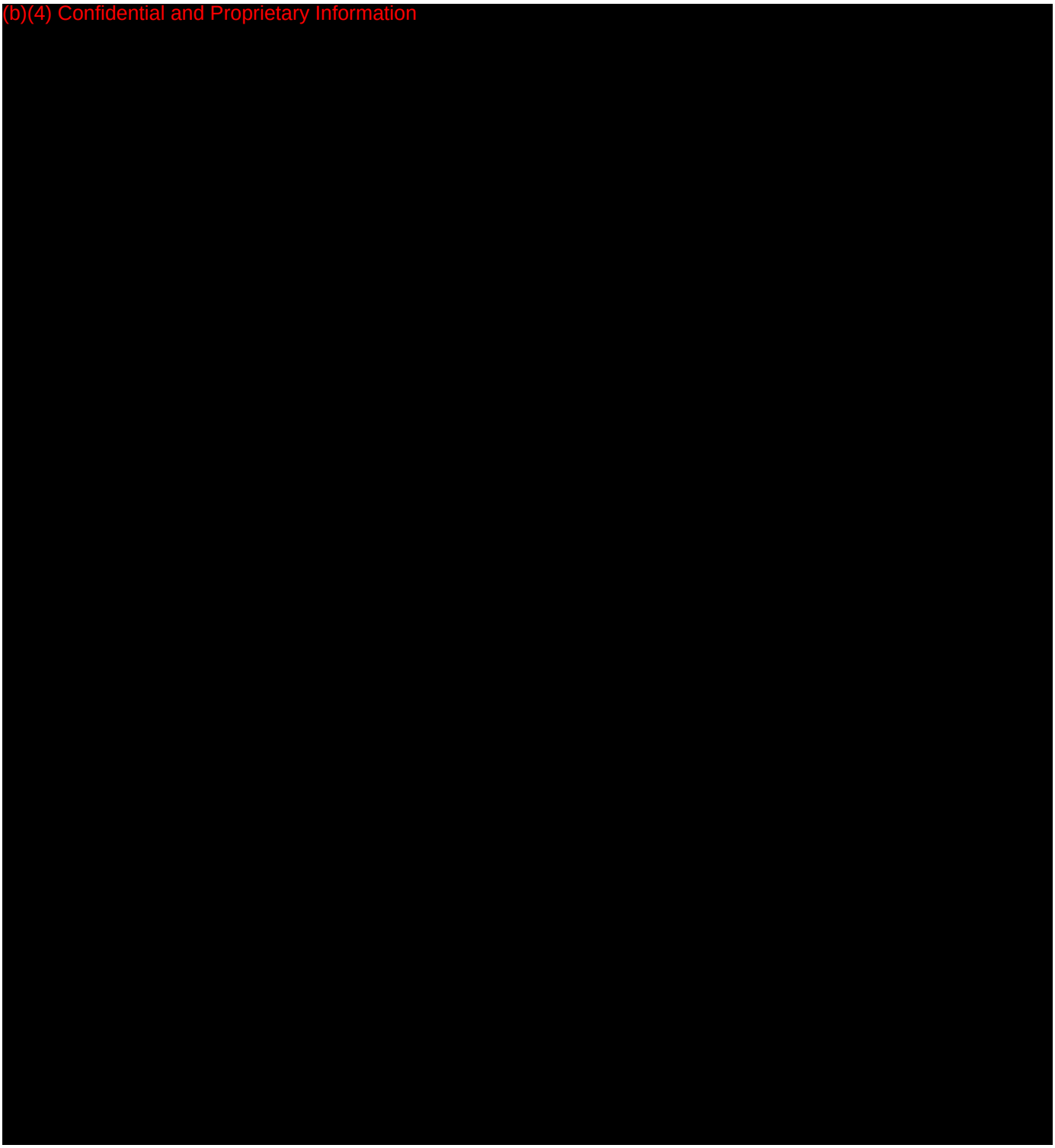
(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



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

(b)(4) Confidential and Proprietary Information

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
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: http://www.fda.gov/oc/mdufma/coversheet.html

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

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) (4)

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)

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
(b)(4) Confidential and Proprietary Information

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?

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

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

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

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

[ ] YES [X] 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)

23-Feb-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Entellus Medical Sinus Guidewire

Indications for Use

To provide a means to access the sinus space for diagnostic and therapeutic procedures.

(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: March 16, 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

Device Information:

Trade Name:	Entellus Medical Sinus Guidewire
Common Name:	Sinus Guidewire
Classification Regulation:	21 CFR 878.4800
Classification Name:	Manual Surgical Instrument for General Use
Classification Panel:	General and Plastic Surgery
Device Classification:	Class I
Product Code:	KAM

Predicate Devices:
NeoMetrics Selectiva™ SB Guidewire [K033321, K013024]
Relieva Vigor™ Sinus Guidewire [K043445]

Device Description:
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a lubricious coating.

Indication for Use
To provide a means to access the sinus space for diagnostic and therapeutic procedures.

Contraindications:
None

Technological Characteristics:
The device has the same technological characteristics (i.e., design, function, materials, biocompatibility, packaging and sterilization) as the predicate device [K033321, K013024]. The device has the same technological characteristics (i.e., design, function, principle of operation, biocompatibility and sterilization) as the predicate device [K043445]. The subject and predicate devices are all sterilized using Ethylene Oxide (EtO), validated per ISO 11135-1, and have a

Sterility Assurance Level (SAL) of 10^{-6}. All devices 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 is the same as the predicate device [K043445]. The technological characteristics of the subject device are the same as the predicate devices, [K033321, K013024] and/or [K043445], including: design, function, principle of operation, materials, biocompatibility, packaging and sterilization.

Performance Data:
Performance testing of the Entellus Medical Sinus Guidewire consisted of design verification testing and a cadaver study. Design verification testing included simulated use and compatibility testing. A cadaver study was conducted to support the utility of this device in the sinus spaces. Biocompatibility, sterilization, packaging, shelf life 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.

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

INSTRUCTIONS FOR USE

Selectiva™ GUIDEWIRES

GUIDES *Selectiva*™

ALAMBRES GUÍA *Selectiva*™

GUIDE *Selectiva*™

Selectiva™ FÜHRUNGSDRÄHTE

NeoMetrics, Inc.
14800 28th Avenue North, Suite 150
Plymouth, MN 55447
Phone: 763 559-4440
Fax: 763 559-7676

Authorized Representative in Europe
Emergo Europe
Molenstraat 15
2513 BH, The Hauge
The Netherlands
Phone: +31.70.345.8570
+31.70.346.7299

CE 0120

SP-2189 Rev A

SP-3025 Rev. C

INSTRUCTIONS FOR USE

Selectiva™ GUIDEWIRES

Caution:

Federal law (USA) restricts this device for sale by or on the order of physician.

- Disposable, For Single Patient Use Only
- Ethylene Oxide (EO) Sterilization, Non-Pyrogenic
- Read all directions prior to use
- Store in a cool, dry place

Warning:

This device is not intended for use in the coronary arteries or the neurovasculature.

Description:

Selectiva Guidewires are constructed of nickel titanium alloys, stainless steel, platinum/tungsten alloys, and feature a lubricious coating.

Indications:

To facilitate the placement of devices for diagnostic and interventional procedures.
NOTE: These guidewires are not intended for PTCA use.

Directions:

A. Inspect the guidewire prior to use for tip shape, bends, kinks or coil separation. Do not use if damaged.
B. Using sterile technique, localize and puncture the vessel with a needle cannula.
C. Remove the needle, leaving the cannula in place.
D. Insert distal end of the guidewire through the cannula and into the vessel.
E. Remove cannula, leaving guidewire within the lumen of the vessel.
F. Pass the catheter over the guidewire within the lumen of the vessel under fluoroscope guidance to the desired position.
G. Carefully remove the guidewire from the catheter.

Cautions:

- Single use only, do not re-sterilize.
- Do not advance Selectiva Guidewires against resistance until the cause of the resistance has been determined.
- Excessive force against resistance may result in damage to guidewire and catheter or vessel perforation.
- Guidewires, by nature of their construction, will collect blood and other foreign matter in lumen. No type of cleaning will completely remove this material. Therefore, they are intended for single patient use only.
- NeoMetrics, Inc. does not recommend a particular technique for the use of this device. The steps contained in the preceding directions discuss the Seldinger Technique for percutaneous entry and are for information purposes only. Each physician should evaluate their appropriateness according to individual patient conditions and his or her medical training and experience.

Quick Links: Skip to main page content Skip to Search Skip to Topics Menu Skip to Section Content Menu Skip to Common Links

510(k) Premarket Notification

510 (k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search Back To Search Results

Device Classification Name	Wire, Guide, Catheter
510(K) Number	K033321
Device Name	SELECTIVA SB GUIDEWIRE
Applicant	NEO METRICS, INC. 14800 28th Avenue North Suite 150 Plymouth, MN 55447
Contact	Mark Pederson
Regulation Number	870.1330
Classification Product Code	DQX
Date Received	10/21/2003
Decision Date	11/05/2003
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No

K033321

NOV - 5 2003

Section 9
510(k) Summary

Submitter:	NeoMetrics, Inc. 14800 28th Avenue South, Suite 150 Plymouth, MN 55447 Telephone: 763-559-4440 Fax: 763-559-7676
Contact Person:	Mark Pederson Product Development Engineer Telephone: 763-559-4440 Fax: 763-559-7676 pedersonm@qwest.net
Date Prepared:	October 14, 2003
Trade Name:	Selectiva SB Guidewire
Classification Name and Number:	Wire, Guide, Catheter 870.1330
Product Code:	DQX
Predicate Device(s):	NeoMetrics *Selectiva*™ Guidewire (K013024) FlexMedics FlexFinder Guidewire (K943390)
Device Description:	The Selectiva SB Guidewires are constructed of a nickel-titanium alloy with a PTFE polymer jacket. Devices are available in a diameter of 0.035 inches and in lengths ranging from 40 to 300 cm.
Intended Use:	The NeoMetrics Selectiva SB Guidewire is intended to facilitate the placement of devices for diagnostic and interventional procedures. NOTE: These guidewires are not intended for PTCA use.
Functional and Safety Testing:	Representative samples of the device underwent bench testing to demonstrate appropriate functional and performance characteristics compared to the predicate device(s).
Conclusion:	The NeoMetrics Selectiva SB Guidewire modified as proposed in this submission, is substantially equivalent to the predicate devices. This conclusion is based upon the similarity in design, principles of operation, materials, and performance of the modified device compared to the originally, cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

NeoMetrics, Inc.
c/o Mr. Mark Pederson
Product Development Engineer
14800 28th Avenue South, Suite 150
Plymouth, MN 55447

Re: K033321
Selectiva SB Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 14, 2003
Received: October 21, 2003

Dear Mr. Pederson:

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 Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Elisa D. Harvey for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

 K033321

Section 3
Indications for Use

The NeoMetrics Selectiva SB Guidewire is intended to facilitate the placement of devices for diagnostic and interventional procedures.
NOTE: These guidewires are not intended for PTCA use.

Prescription Use X
(Per 21 CFR 801.109)

1/4/05

Division of Cardiovascular & Respiratory Devices
510(k) Number K033321

Quick Links: Skip to main page content Skip to Search Skip to Topics Menu Skip to Section Content Menu Skip to Common Links

510(k) Premarket Notification

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search Back To Search Results

Device Classification Name	Wire, Guide, Catheter
510(K) Number	K013024
Device Name	SELECTIVA GUIDEWIRE
Applicant	NEO METRICS, INC. 15301 Highway 55 West Minneapolis, MN 55447
Contact	Gene Champeau
Regulation Number	870.1330
Classification Product Code	DQX
Date Received	09/07/2001
Decision Date	12/04/2001
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Section 8
Summary of Safety and Effectiveness

K013024

DEC 0 4 2001

Submitter

NeoMetrics, Inc.
15301 Highway 55 West
Plymouth, MN 55447
Telephone: (763) 559-4440
Fax: (763) 559-7676
Contact Person: Gene Champeau, President
Date: August 31, 2001

Product

Classification Name:	Catheter Guidewire (21 CFR 870.1330)
Common Name:	Guidewire, catheter guidewire, and wire guide
Trade/Proprietary Name:	*Selectiva*™ Guidewire

Substantially Equivalent Product

Lake Region Manufacturing Mandrel Guidewire Assembly (K011084).

Description

The *Selectiva*™ Guidewire is used to facilitate the placement of devices for diagnostic and interventional procedures. The shaft of the device is constructed of PES (polyethersulfone) coated Nitinol or stainless steel with a tapered distal end secured to a platinum or stainless steel helical coil. A selection of distal tapers imparts different tip flexibilities. The guidewire is coated with silicone fluid to improve lubricity.
The *Selectiva*™ Guidewire will be offered in diameters of 0.018" – 0.035" and lengths of 60 cm – 260 cm. It will be supplied sterile, intended for one-time use.

Indications for Use

To facilitate the placement of devices for diagnostic and interventional procedures.
NOTE: These guidewires are not intended for PTCA use.

Physical Characteristics

The *Selectiva*™ Guidewire and the predicate device were compared in all functional and safety tests including dimensional, visual, tip flexibility, tensile strength, torqueability, and coating durability, to demonstrate equivalency in terms of safety and effectiveness. Biocompatibility testing of finished devices has been successfully completed in addition to the independent laboratory testing demonstrating equivalence of materials.

Conclusion

Based on performance data and comparisons of intended use, labeling, and design, the *Selectiva*™ Guidewire is considered substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gene Champeau
President
NeoMetrics, Inc.
15301 Highway 55 West
Plymouth, MN 55447

DEC 0 4 2001

Re: K013024
Seletiva™ Guidewire
Regulation Number: 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: September 6, 2001
Received: September 7, 2001

Dear Mr. Champeau:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3
Indications for Use

K013074

The NeoMetrics *Selectiva*™ Guidewire is intended to facilitate the placement of devices for diagnostic and interventional procedures.
NOTE: These guidewires are not intended for PTCA use.

Division of Cardiovascular & Respiratory Devices
510(k) Number K013074

Prescription Use ✓
(Per 21 CFR 801.109)

Acclarent™

Instructions for Use

Relieva Vigor™

Sinus Guidewire

IFU005031 Rev A Effective Date 4/13/2009

Acclarent

Instructions for Use

Relieva Vigor™ Sinus Guidewire

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 Vigor* Sinus Guidewire is sterilized with ethylene oxide gas.

SINGLE USE: The *Relieva Vigor* Sinus Guidewire is intended for single patient use only. DO NOT resterilize and/or reuse.

STORAGE: Store in a cool, dry place.

DESCRIPTION

The *Relieva Vigor* Sinus Guidewire is a 0.035"- compatible Sinus Guidewire with a pre-shaped radiopaque distal tip and lubricious coating. The *Relieva Vigor* Sinus Guidewire may also have one or more shaft marker bands.

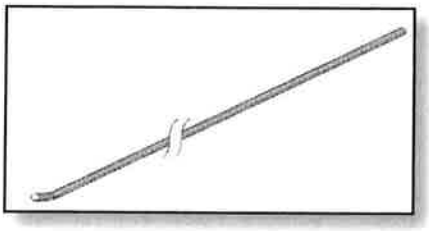

Figure 1

INDICATIONS FOR USE

The *Relieva Vigor* Sinus Guidewire is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

CONTRAINDICATIONS

Not for use during any other procedures than indicated.

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 a Sinus Guidewire against unknown resistance as this could cause tissue trauma or device damage.

PRECAUTIONS

Do not attempt to alter the pre-shaped distal tip of the *Relieva Vigor* Sinus Guidewire, as this may result in device damage.

COMPATIBILITY

The *Relieva Vigor* Sinus Guidewire is compatible with the *Balloon Sinuplasty*™ System *Relieva*® devices.

INSTRUCTIONS FOR USE

1. Flush the protective hoop with sterile saline or water.
2. Remove the *Relieva Vigor* Sinus Guidewire from the protective hoop.

If used in conjunction with a Sinus Guide Catheter:

1. Insert the *Relieva Vigor* Sinus Guidewire through the Sinus Guide Catheter and advance into the target sinus until some light resistance is felt. **DO NOT USE EXCESSIVE FORCE.**
2. If significant resistance is encountered, retract the *Relieva Vigor* Sinus Guidewire and slightly change the position (rotate in either direction). Again advance the *Relieva Vigor* Sinus Guidewire in a gentle, probing motion.
3. Confirm placement and position of the *Relieva Vigor* Sinus Guidewire with endoscopic and/or fluoroscopic visualization.

GRAPHIC SYMBOLS CONTAINED ON DEVICE LABELING

LOT	Batch Code	Rx ONLY	On Order of Physician Only
STERILE EO	Sterilized Using Ethylene Oxide		Date of Manufacture
	Use By		Consult Instructions For Use
	Do Not Re-Use		Diameter Compatibility
	Length	θ	Tip Shape
	Keep dry		Maximum Temperature
	Keep Away from Sunlight	CE 0123	CE Mark
EC REP	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.

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

Acclarent, Inc., 1525-B O'Brien Drive, Menlo Park, CA 94025
Customer Service: 1-877-SPLASTY
+1-650-687-5888
www.acclarent.com

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CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search

No records were found with
KNumber: K043445

K071815

Acclarent

SEP 28 2007

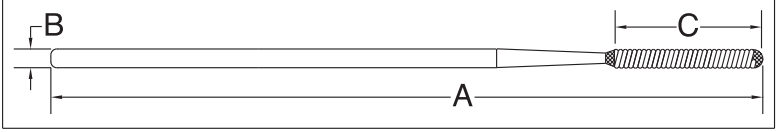
APPENDIX A: 510(k) SUMMARY

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*™ 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*™ Sinus Guidewire (K043445)
Device Description:	The *Relieva Luma*™ 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*™ 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*™ 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*™ Sinus Illumination System met all performance testing acceptance criteria.
Summary of Substantial Equivalence:	The *Relieva Luma*™ Sinus Illumination System is substantially equivalent to the predicate device as confirmed through relevant performance tests.

entellus MEDICAL™

Sinus Guidewire

A Length	B Diameter	C Tip
80cm	.035”	ANGLED



REF **SGW-100** MODEL # **PTW** LOT **XXXXX**

See Instructions For Use

Store In Cool Dry Place

Non-pyrogenic

Do Not Autoclave

Keep Dry

STERILE EO

Single Use

Manufactured in the U.S.A.

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

Use By:

Quantity:

entellus MEDICAL™

Manufactured By:
Entellus Medical
6705 Wedgwood Court North
Maple Grove, MN 55311
866-620-7615
Fax: 866-620-7616

SP-3461 Rev. A

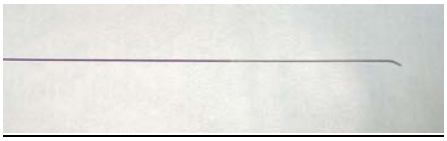
entellus MEDICAL™
Sinus Guidewire
Length 80cm
Diameter .035”
Tip ANGLED
Use By: xxxx
MODEL # PTW

INSTRUCTIONS FOR USE
Entellus Medical Sinus Guidewire

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, Non-Pyrogenic
Single Use: Disposable, For Single Patient Use Only, Do Not Resterilize and/or Reuse
Storage: Store in a cool, dry place

Description
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a lubricious coating.



Indication For Use
To provide a means to access the sinus space for diagnostic and therapeutic procedures.

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.
- Only surgeons trained in the use of sinus guidewires should use this device.
- Never advance or withdraw the device against unknown resistances as this can cause tissue trauma or device damage.

Precautions
- Due to the variability of sinus anatomy, review radiographic imaging (CT scan) prior to the procedure to understand anatomy.
- If fluoroscopy is used, minimize radiation dose to the lens of the eye and other proliferating tissues due to the potential of cataract formation or injury to the surrounding tissue.

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 Entellus Medical Sinus Guidewire is compatible with instruments (malleable suctions, guide catheters, sinus cannulas) having OD ≥ 2mm and with balloon catheters having an internal lumen with a diameter of ≥ 0.035".

Instructions for Use

1. Remove the sinus guidewire from the protective hoop.
2. Under endoscopic visualization:
   a. Place a guide (or curved suction or sinus cannula) into the desired anatomy.
   b. Track the sinus guidewire through the guide into the target sinus space until light resistance is felt. Do not use excessive force.
   c. If significant resistance is encountered, retract the sinus guidewire. Change the position of the guide or rotate the angled tip in either direction and advance again in a gentle motion.
3. Confirm guidewire is located in target sinus space with endoscopic and/or fluoroscopic visualization.
4. 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, 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 as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical, Inc.'s control, directly affect the device and the results obtained from its use. Entellus Medical, Inc. 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, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Graphic Symbols Contained on Device labeling

REF Reorder Number	LOT Lot Number	MODEL Model Number
 See Instructions For Use	 Keep Dry	 Do Not Reuse
STERILE EO Sterilization with Ethylene Oxide Gas	 Use By	Rx Only Prescription Use Only
 Quantity	 Manufacturer	 Store in Cool Dry Place

Manufactured by:
Entellus Medical Inc.
6705 Wedgwood Court North
Maple Grove, MN 55311
(763) 463-1595
www.entellusmedical.com

(b)(4) Confidential and Proprietary Information

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Susan Rudy, CRNP

Subject: 510(k) Number K110739

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)

☐ Hold (Additional Information or Telephone Hold).

X Final Decision (**SE**, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE *no response*
☐	NH	NSE for another reason

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

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

Regulation Number	**Class***	**Product Code**
21 CFR 874.4420	Class I	LRC

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

Additional Product Codes: _____

Review: _____ ENT B 6/13/11
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 6/14/11
(Division Director) (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

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

K110739 / A002

Date: 6/1/2011
To: The Record
From: Susan Rudy, MSN, CRNP, CORLN

Office: ODE
Division: DONED / ENTB

510(k) Holder: Entellus Medical, Inc.
Device Name: Entellus Medical Sinus Guide (Model PTW)
Contact: Karen Peterson, Vice President, Clinical, Regulatory and Quality
Phone: 763 463 7056
Fax: 763 463 1599
Email: Kpeterson@entellusmedical.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Entellus Medical Sinus Guide (Model PTW) into interstate commerce.

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

II. Administrative Requirements

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

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?	√		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		√√	

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

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[redacted]

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?		X	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?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See
http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWC

(b)(4) Confidential and Proprietary Information

XVII. Recommendation – SE

Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC

Susan Rudy CRNP
Susan F. Rudy, MSN, CRNP, CORLN — 6/2/2011 Date

Srinivas Nandkumar, PhD., ENTB Chief — 6/12/11 Date

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Entellus Medical Sinus Guidewire
K-110739 /A001
Entellus Medical

510 (k) Clinical Review (K- 110739)

Date: 05-31-2011

TO: Susan Rudy, MSN, CRNP, CORLN, OCN
Nurse Consultant & Family Nurse Practitioner
ENTB/ODE/DONED

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

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

Subject: **Entellus Medical Sinus Guidewire**

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

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(b)(4) Confidential and Proprietary Information and (b)(5)

K110739/A002

entellus MEDICAL™

510(k) Summary

Date Prepared: May 14, 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

Device Information:

Trade Name:	Entellus Medical Sinus Guidewire
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 Devices:
NeoMetrics Selectiva™ SB Guidewire [K033321, K013024]
Relieva Vigor™ Sinus Guidewire [K043445]

Device Description:
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a polymer coating.

Indication for Use
To provide a means to access the frontal, sphenoid and maxillary sinuses, for diagnostic and therapeutic procedures in adults aged 18 and over.

Contraindications:
None

Technological Characteristics:
The device has the same technological characteristics (i.e., design, function, materials, biocompatibility, packaging and sterilization) as the predicate device [K033321, K013024]. The device has the same technological characteristics (i.e., design, function, principle of operation, and biocompatibility) as the predicate device [K043445]. The subject and predicate devices are

all sterilized using Ethylene Oxide (EtO), validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of 10^{-6}. All devices 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 is the same as the predicate device [K043445]. The technological characteristics of the subject device are the same as the predicate devices, [K033321, K013024] and/or [K043445], including: design, function, principle of operation, materials, biocompatibility, packaging and sterilization.

Performance Data:
Performance testing of the Entellus Medical Sinus Guidewire consisted of design verification testing and a cadaver study. Design verification testing included simulated use and compatibility testing. A cadaver study was conducted to support the utility of this device in the sinus spaces. Biocompatibility, sterilization, packaging, shelf life 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.

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K110739/A002

Instructions for Use

1. Remove the sinus guidewire from the protective hoop.
2. Under endoscopic visualization:
   a. Place a guide (or curved suction or sinus cannula) into the desired anatomy.
   b. Track the sinus guidewire through the guide into the target sinus space until light resistance is felt. Do not use excessive force.

   NOTE: If significant resistance is encountered while advancing or withdrawing the guidewire, change the position of the guide or rotate the angled tip of the guidewire in either direction, then advance or withdraw the guidewire in a gentle motion.
3. Confirm guidewire is located in target sinus space with endoscopic and/or fluoroscopic visualization.
4. 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, Inc. 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, Inc.'s control, directly affect the device and the results obtained from its use. Entellus Medical, Inc. 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, Inc. 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

REF Reorder Number	LOT Lot Number	MODEL Model Number
 See Instructions For Use	 Keep Dry	 Do Not Reuse
STERILE EO Sterilization with Ethylene Oxide Gas	 Use By	Rx Only Prescription Use Only
 Quantity	 Manufacturer	 Store in Cool Dry Place

Solo Pro is a trademark of Acclarent, Inc.
Xpress is a trademark of Entellus Medical, Inc.

Manufactured by:
Entellus Medical Inc.
6705 Wedgwood Court North
Maple Grove, MN 55311
(763) 463-1595
www.entellusmedical.com

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K110739 / A001

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	User Fee Payment ID Number	FDA Submission Document Number (if known)
March 16, 2011	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other
☐ Supplement	☐ Supplement			*(describe submission):*
	☐ Report			
	☐ Report Amendment			

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

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

ECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

Request for Removal of Applicant Hold

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
- ☐ Conditional Approval
- ☐ Deemed Approved
- ☐ Deficient Final Report
- ☐ Deficient Progress Report
- ☐ Deficient Investigator Report
- ☐ Disapproval
- ☐ Request Extension of Time to Respond to FDA
- ☐ Request Meeting
- ☐ Request Hearing

Manufacturer

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DQX	2	KAM	3		4	
5		6		7		8	

Summary of, or statement concerning, **safety and effectiveness information**

- ☒ 510 (k) summary attached
- ☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K033321, K013024		Selectiva™ SB Guidewire		NeoMetrics, Inc.
2	K043445		Relieva Vigor™ Sinus Guidewire		Acclarent, Inc.
3					
4		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Common name: Sinus Guidewire
Classification name: Manual Surgical Instrument for General Use

	Trade or Proprietary or Model Name for This Device		Model Number
1	Entellus Medical Sinus Guidewire	1	PTW
2		2	

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	C.F.R. Section *(if applicable)*	Device Class
LRC	21 CFR 874.4420	☒ Class I ☐ Class II ☐ Class III ☐ Unclassified
Classification Panel		
ENT		

Indications *(from labeling)*

To provide a means to access the sinus space for diagnostic and therapeutic procedures in adults aged 18 and over.

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

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

(b)(4) Confidential and Proprietary Information

[redacted]

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.

(b)(4) Confidential and Proprietary Information

[redacted]

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

(b)(4) Confidential and Proprietary Information and (b)(5)

(b)(4) Confidential and Proprietary Information and (b)(5)

K110739/ A001

TO: Susan Rudy, FDA ENTB team leader
FROM: Karen Peterson, Entellus Medical
RE: Response to K110739 interactive review deficiencies of 5-13-11
DATE: 5-16-11

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

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(b)(4) Confidential and Proprietary Information and (b)(5)

(b)(4) Confidential and Proprietary Information and (b)(5)

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Entellus Medical Sinus Guidewire

Indications for Use

To provide a means to access the sinus space for diagnostic and therapeutic procedures 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_____

K110739/A001

entellus MEDICAL™

510(k) Summary

Date Prepared:	May 14, 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
Device Information:	
Trade Name:	Entellus Medical Sinus Guidewire
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 Devices:
NeoMetrics Selectiva™ SB Guidewire [K033321, K013024]
Relieva Vigor™ Sinus Guidewire [K043445]

Device Description:
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a lubricious coating.

Indication for Use
To provide a means to access the sinus space for diagnostic and therapeutic procedures in adults aged 18 years and over.

Contraindications:
None

Technological Characteristics:
The device has the same technological characteristics (i.e., design, function, materials, biocompatibility, packaging and sterilization) as the predicate device [K033321, K013024]. The device has the same technological characteristics (i.e., design, function, principle of operation, and biocompatibility) as the predicate device [K043445]. The subject and predicate devices are

all sterilized using Ethylene Oxide (EtO), validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of 10^{-6}. All devices 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 is the same as the predicate device [K043445]. The technological characteristics of the subject device are the same as the predicate devices, [K033321, K013024] and/or [K043445], including: design, function, principle of operation, materials, biocompatibility, packaging and sterilization.

Performance Data:
Performance testing of the Entellus Medical Sinus Guidewire consisted of design verification testing and a cadaver study. Design verification testing included simulated use and compatibility testing. A cadaver study was conducted to support the utility of this device in the sinus spaces. Biocompatibility, sterilization, packaging, shelf life 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.

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

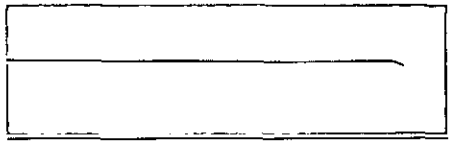
entellus MEDICAL

INSTRUCTIONS FOR USE
Entellus Medical Sinus Guidewire

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, Non-Pyrogenic
Single Use: Disposable, For Single Patient Use Only, Do Not Resterilize and/or Reuse
Storage: Store in a cool, dry place

Description
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a lubricious coating.



Indication For Use
To provide a means to access the sinus space for diagnostic and therapeutic procedures 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.

Precautions
- Due to the variability of sinus anatomy, review radiographic imaging (CT scan) prior to the procedure to understand anatomy.
- If fluoroscopy is used, follow standard hospital guidelines and requirements for proper fluoroscopic use.
- Do not attempt to alter the angulation of the guidewire tip as this may result in device damage.

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 Entellus Medical Sinus Guidewire is compatible with instruments (malleable suctions, guide catheters, sinus cannulas) having OD ≥ 2mm and with balloon catheters having an internal lumen with a diameter of ≥ 0.035". Examples of devices that meet these requirements include Xpress™ Multi-Sinus Dilation Tool, Solo Pro™ Sinus Balloon Catheter, and Medtronic, Inc. MCSK5 Suction Tube.

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Instructions for Use

1. Remove the sinus guidewire from the protective hoop.
2. Under endoscopic visualization:
   a. Place a guide (or curved suction or sinus cannula) into the desired anatomy.
   b. Track the sinus guidewire through the guide into the target sinus space until light resistance is felt. Do not use excessive force.

   NOTE: If significant resistance is encountered while advancing or withdrawing the guidewire, change the position of the guide or rotate the angled tip of the guidewire in either direction, then advance or withdraw the guidewire in a gentle motion.
3. Confirm guidewire is located in target sinus space with endoscopic and/or fluoroscopic visualization.
4. 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, Inc. 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, Inc.'s control, directly affect the device and the results obtained from its use. Entellus Medical, Inc. 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, Inc. 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

REF Reorder Number	LOT Lot Number	MODEL Model Number
 See Instructions For Use	 Keep Dry	 Do Not Reuse
STERILE EO Sterilization with Ethylene Oxide Gas	 Use By	Rx Only Prescription Use Only
 Quantity	 Manufacturer	 Store in Cool Dry Place

Solo Pro is a trademark of Acclarent, Inc.
Xpress is a trademark of Entellus Medical, Inc.

Manufactured by:
Entellus Medical Inc.
6705 Wedgwood Court North
Maple Grove, MN 55311
(763) 463-1595
www.entellusmedical.com

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Acclarent

K061903

APPENDIX A: 510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Keri Yen Quality Engineer Phone: (650) 687-5874 Fax: (650) 687-5889
Date of Submission:	June 30, 2006
Device Trade Name:	To be determined
Common Name:	Sinus Balloon Catheter—Integrated Wire
Device Classification:	Class I
Regulation Number:	21 CFR 874.4420
Classification Name:	ENT Manual Surgical Instrument
Product Code:	LRC
Predicate Device:	Relieva Sinus Balloon Catheter (K043527) Relieva Sinus Guidewire (K043445)
Device Description:	The Sinus Balloon Catheter—Integrated Wire is a sinus balloon catheter that has an integrated guidewire. The Sinus Balloon Catheter—Integrated Wire allows access to and dilation of the sinus ostia and paranasal spaces with a single device.
Indications for Use:	To provide a means to access the sinus space and to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.
Technological Characteristics	The Sinus Balloon Catheter—Integrated Wire is a device that allows for the capability to access and to dilate the sinus ostia with the same device.
Performance Data	The Sinus Balloon Catheter—Integrated Wire met all performance testing acceptance criteria.
Summary of Substantial Equivalence:	The Sinus Balloon Catheter—Integrated Wire is substantially equivalent to the predicate devices as confirmed through relevant performance tests.

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Acclarent

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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*™ 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*™ Sinus Guidewire (K043445)
Device Description:	The *Relieva Luma*™ 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*™ 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*™ 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*™ Sinus Illumination System met all performance testing acceptance criteria.
Summary of Substantial Equivalence:	The *Relieva Luma*™ Sinus Illumination System is substantially equivalent to the predicate device as confirmed through relevant performance tests.

Click Image to Enlarge

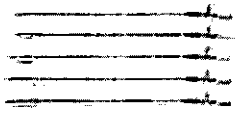
Relieva Vigor® Sinus Guidewire

The *Relieva Vigor*® Sinus Guidewire - the latest addition to the *Relieva*® Sinus Guidewire family - delivers the consistent, precise steering required to navigate unique and tortuous anatomy in multi-sinus cases. This latest advance in Sinus Guidewire technology is engineered for resilient and responsive performance throughout each case, from the first sinus to the last.

Click Image to Enlarge

Relieva Luma® Sinus Illumination System

The *Relieva Luma*® Sinus Illumination System presents an innovative option for confirming sinus access for ostial dilation. Harnessing unique trans-sinus illumination technology, the *Relieva Luma*® Sinus Illumination System delivers a remarkable combination of full-strength, targeted fiberoptic light transmission and agile device handling. The *Relieva Luma*® Sinus Illumination System is compatible with all existing *Relieva*® products.



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Relieva Solo™ Sinus Balloon Catheter*

The *Relieva Solo*™ is the latest-generation Sinus Balloon Catheter from Acclarent, bringing a new level of performance and precision to sinus dilation. The advanced, compact design fuses the flexibility of a catheter for navigating tortuous sinus anatomy with the balance and responsive feel of a traditional surgical instrument.

Click Image to Enlarge

Relieva® Sinus Guide Catheter*

The *Relieva*® Sinus Guide Catheter is a semi-flexible tube with a malleable shaft that is placed near a sinus ostium. Under endoscopic guidance, it facilitates placement of other devices into or near the sinus.

Click Image to Enlarge

Relieva® Extension Tubing (High Pressure)

Relieva® Extension Tubing provides a high-pressure connection between the *Acclarent*™ Balloon Inflation Device and Balloon Catheters for those desiring additional working freedom.

Click Image to Enlarge

Acclarent™ Balloon Inflation Device

The *Acclarent*™ Balloon Inflation Device is used to control the inflation and deflation of the various *Acclarent*™ Balloon Catheters.

Click Image to Enlarge

* Not available for sale in the US

Acclarent

Overview

Sinusitis

Airway Stenosis

Products
- Balloon Sinuplasty System
- Inspira AIR System
- Product Catalog
- Instructions For Use

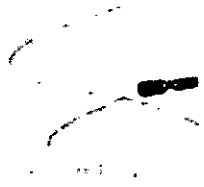
Solutions

Home > Solutions > Products > Balloon Sinuplasty System

Balloon Sinuplasty™ System

The *Balloon Sinuplasty*™ System

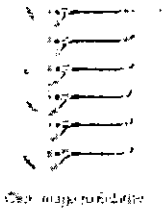
Using endoscopic techniques, the *Balloon Sinuplasty*™ system enables qualified otolaryngologists to dilate obstructed sinus ostia in patients suffering from sinusitis. The system is based on flexible catheter and wire technology specifically designed to navigate the tortuous sinus anatomy with minimal trauma. All 510(k) products have been cleared by the U.S. Food and Drug Administration.



Relieva Luma Sentry™ Sinus Illumination System & Accessories

The *Relieva Luma Sentry*™ Sinus Illumination System provides confident direct visual confirmation of sinus access via transcutaneous illumination. The new *Relieva Luma Sentry*™ Sinus Illumination System improves product ease of use and drives procedural efficiencies enabling fast and easy sinus access, dilation and irrigation. The *Relieva Luma Sentry*™ Sinus Illumination System is compatible with all existing *Relieva* Balloon Sinuplasty™ Products.

Learn More



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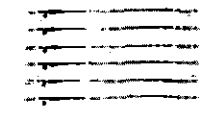
Relieva Flex™ Sinus Guide Catheter

The *Relieva Flex*™ Sinus Guide Catheter is designed to enable faster, easier, and less traumatic sinus access by incorporating suction and a softer distal tip.



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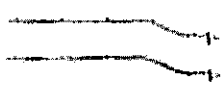
Relieva Solo Pro™ Sinus Balloon Catheter

Relieva Solo Pro™ is the next generation Sinus Balloon Catheter, incorporating the latest technology advancements from Acclarent. Combining proven balloon catheter technology with recent innovation, *Relieva Solo Pro*™ takes performance and precision to the next level.

Click image to Enlarge

Relieva Vortex® Sinus Irrigation Catheter

The *Relieva Vortex*® Sinus Irrigation Catheter is a uniquely designed catheter for the challenges associated with flushing tenacious sinus contents. With its flexible yet durable construction and advanced side-jet delivery, the *Relieva Vortex*® Sinus Irrigation Catheter combines the power of deep intra-sinus delivery and strong shear flows to empty sinus contents.



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Relieva Sidekick Low Profile™ *and Relieva Sidekick*™ Sinus Guide Catheter Handles

The *Relieva Sidekick*™ Low Profile Sinus Guide Catheter Handle and *Relieva Sidekick*™ Sinus Guide Catheter Handle enable continuous, direct visualization as you use *Relieva*® *Balloon Sinuplasty*™ devices, delivering a means for easy handling of endoscope and instruments in tandem.