



Food and Drug Administration  
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October 24, 2016

Acclarent, Inc.  
Ms. Anna Hwang  
Regulatory Affairs Specialist  
33 Technology Drive  
Irvine, CA 92618

Re: K161697

Trade/Device Name: Acclarent Navwire Sinus Navigation Guidewire  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: PGW  
Dated: September 21, 2016  
Received: September 22, 2016

Dear Ms. Hwang:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

  
**Eric A. Mann -S**

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

Enclosure

**Indications for Use**

510(k) Number (if known)

K161697

Device Name

Acclarent® NavWire Sinus Navigation Guidewire

Indications for Use (Describe)

The Acclarent NavWire is intended for use as a navigable guidewire to provide access to nasal and sinus spaces, and confirmation of placement in the accessed anatomy. The Acclarent NavWire is designed for use during procedures where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, can be identified relative to a CT-based model of the anatomy.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

<b>Sponsor/Submitter:</b>	Acclarent, Inc. 33 Technology Drive Irvine, CA 92618
<b>Contact Person:</b>	Anna Hwang Regulatory Affairs Specialist Email: ahwang@its.jnj.com Telephone: 949-923-4134 Mobile: 310-780-8792
<b>Date of Submission:</b>	June 17, 2016
<b>Device Trade Name:</b>	Acclarent® NavWire Sinus Navigation Guidewire
<b>Common Name:</b>	Image Guided Surgery System
<b>Device Classification:</b>	Class II
<b>Regulation Number:</b>	21 CFR 882.4560
<b>Classification Name:</b>	Ear, Nose, and Throat Stereotaxic Instrument
<b>Product Code:</b>	PGW
<b>Predicate Device:</b>	The Fiagon Navigation Extended Instrument Set ENT (K141456) Relieva Spin Sinus Dilation System (K111875)
<b>Device Description:</b>	The Acclarent® NavWire Sinus Navigation Guidewire an electromagnetically (EM) trackable guidewire that provides surgeons a means to access the intranasal and paranasal sinus spaces in endoscopic and image guided sinus surgeries. It is compatible with the CARTO® ENT System to track the NavWire within an electromagnetic field, which displays the magnetic sensor position relative to a patient's pre-operative CT scan.
<b>Indications for Use:</b>	The Acclarent® NavWire Sinus Navigation Guidewire is intended for use as a navigable guidewire to provide access to nasal and sinus spaces, and confirmation of placement in the accessed anatomy. The Acclarent® NavWire Sinus Navigation Guidewire is designed for use during procedures where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, can be identified relative to a CT-based model of the anatomy.
<b>Technological Characteristics:</b>	The Acclarent® NavWire Sinus Navigation Guidewire and its predicate utilize electromagnetic image-guided sinus surgery and are used in

conjunction with a compatible surgical navigation system which consists of computer-aided software, CT-imaging, patient tracker, registration probe, and various instruments used in sinus surgery. Acclarent® NavWire Sinus Navigation Guidewire provides real-time tracking at the distal tip of the guidewire in the nasal anatomy.

**Performance Data:**

Bench testing was performed in order to determine device accuracy and precision. The following nonclinical tests were performed to determine substantial equivalence:

- Nonclinical accuracy testing of the Acclarent® NavWire Sinus Navigation Guidewire with the CARTO® ENT System
- Nonclinical performance testing of the Acclarent® NavWire Sinus Navigation Guidewire with the CARTO® ENT System
- Functionality of the Acclarent® NavWire Sinus Navigation Guidewire after accelerated aging and user conditions
- Simulated use testing of the NavWire with the CARTO® ENT System according to user's needs and intended use
- Sterilization verification to effectively EtO sterilize the NavWire (SAL  $10^{-6}$ ) and EtO residuals are within defined limits
- General requirements and performance testing of Acclarent® NavWire Sinus Navigation Guidewire to assure conformance with identified design and performance specifications

The Acclarent NavWire passed all intended criteria in accordance with appropriate test criteria and standards.

**Summary of Substantial Equivalence:**

The Acclarent® NavWire Sinus Navigation Guidewire is substantially equivalent to the predicate device Fiagon Navigation Extended Instrument Set ENT (K141456) and reference device Relieva Luma Sentry® Sinus Illumination System, cleared as part of the Relieva Spin Sinus Dilation System (K1118755). Like the predicate device, the Acclarent® NavWire Sinus Navigation Guidewire is an electromagnetically trackable guidewire which can be used to navigate tortuous sinus anatomy when used in conjunction with an ENT software application for computer assisted surgery. NavWire, like the predicate and reference devices, consists of a long flexible guidewire with a distal tip used to provide access to nasal and sinus spaces, and confirmation of placement in the accessed anatomy. The proposed navigation wire is similar in connectivity, technological characteristics, intended use, and design as the predicate device.

The primary differences between the Acclarent® NavWire Sinus Navigation Guidewire and predicate device do not raise new issues of safety and effectiveness.