May 3, 2019

Acclarent, Inc.
Leena Sorathia
Sr. Regulatory Affairs Specialist
33 Technology Drive
Irvine, California 92618

Re: K190532
Trade/Device Name: TruDi NAV Wire
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: PGW
Dated: March 1, 2019
Received: March 4, 2019

Dear Leena Sorathia:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190532

Device Name

TruDi™ NAV Wire

Indications for Use *(Describe)*

TruDi™ NAV Wire is intended for use as an electromagnetically navigable guidewire to provide access and confirmation of placement in the patient anatomy. The device is intended for use during ENT procedures where reference to a rigid anatomical structure 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

[807.92(a)(1)] Submitter Information

Sponsor/Submitter: Acclarent, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person: Leena Sorathia
Sr. Regulatory Affairs Specialist
Email: lsorathi@its.jnj.com
Tel: 949-923-4118

Date Summary Prepared: May 3, 2019

[807.92(a)(2)] Name of Device

Device Trade Name:	TruDi™ NAV Wire
Classification Name:	Stereotaxic Instrument
Common Name:	Image Guided Surgery System
Device Classification:	Class II
Regulation Number:	21 CFR 882.4560
Review Panel:	Ear, Nose, and Throat
Product Code:	PGW

[807.92(a)(3)] Legally Marketed Devices

Predicate Device: Acclarent® NavWire Sinus Navigation Guidewire, (K161697)

Reference Device: Relieva SpinPlus® Nav Balloon Sinuplasty System, (K171687)

[807.92(a)(4)] Device Description

Device Description: The subject device, TruDi™ NAV Wire, is a single-use electromagnetically (EM) navigated, flexible guidewire, which is compatible for use with the TruDi™ Navigation System to provide access and confirmation of placement in patient anatomy during intranasal and paranasal surgeries. The TruDi™ NAV Wire is intended to provide real-time tracking at the distal tip of the guidewire in the nasal anatomy and is intended to be used during ENT procedures where reference to a rigid anatomical structure can be identified relative to a CT-based model of the anatomy. The subject device, TruDi™ NAV Wire, may be used with compatible non-ferromagnetic instruments that have a lumen of greater than 1mm in diameter and a luer lock mechanism to fix the wire onto the instrument.

The subject device, TruDi™ NAV Wire, is a modification to the predicate device, Acclarent® NavWire Sinus Navigation Guidewire (K161697), and is similar to the guidewire construction of the reference device, Relieva SpinPlus® Nav Balloon Sinuplasty System (K171687). The TruDi™ NAV Wire, like the predicate Acclarent® NavWire Sinus Navigation Guidewire and reference Relieva SpinPlus® Nav Balloon Sinuplasty System consists of a 0.035" EM navigable guidewire with an EM trackable sensor incorporated at the distal tip to provide access to a rigid anatomical structure that can be identified relative to a CT-based model of the anatomy, and confirm placement in the accessed anatomy when used with the TruDi™ Navigation System. The same EM trackable sensor used in the subject TruDi™ NAV Wire device was cleared in the predicate Acclarent® NavWire Sinus Navigation Guidewire (K161697) and reference Relieva SpinPlus® Nav Balloon Sinuplasty System (K171687).

[807.92(a)(5)] Intended Use

Indications for Use:

The TruDi™ NAV Wire is intended for use as an electromagnetically navigable guidewire to provide access and confirmation of placement in the patient anatomy. The device is intended for use during ENT procedures where reference to a rigid anatomical structure can be identified relative to a CT-based model of the anatomy.

Difference in Indications from Predicate Device

The indications for use statement of the subject TruDi™ NAV Wire device is similar to the predicate NavWire device (K161697). The subject and predicate devices are both indicated for use in ENT procedures where image-guided surgery is used to provide access to the patient anatomy and to confirm placement of the device in the accessed anatomy.

The subject device is compatible with non-ferromagnetic instruments that have a lumen of greater than 1mm in diameter and a luer lock mechanism to fix the wire onto the instrument. Whereas, the predicate device is compatible with the RELIEVA ULTIRRA Nav™ Sinus Balloon Catheter (K161698).

The changes in indications for use of the subject device do not raise any significant issues of safety and effectiveness when used as labeled, as demonstrated by performance testing.

The difference in indications for use between the subject device and the predicate/reference devices is supported is presented in Table 1 of this summary.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:

The subject TruDi™ NAV Wire device is a modification to the predicate NavWire device (K161697) and is similar to the guidewire construction of the reference SpinPlus Nav device (K171687).

The subject TruDi™ NAV Wire device, like the predicate NavWire device and reference SpinPlus Nav device, consists of a 0.035" EM navigable guidewire with an EM trackable sensor incorporated at the distal tip to provide confirmation in the accessed anatomy when used with the TruDi™ Navigation System. The same EM trackable sensor used in the TruDi™ NAV Wire device was cleared in the predicate NavWire device (K161697) and reference SpinPlus Nav device (K171687).

Similar to the reference SpinPlus Nav device, the subject TruDi™ NAV Wire device consists of a fixed proximal connector, a flexible spiral coil instrument body, and a pre-shaped atraumatic distal tip housing a sensor. Like the reference SpinPlus Nav device, the subject device incorporates a feature, which allows rotation of the distal tip of guidewire for steering functionality.

The TruDi™ NAV Wire, like the predicate NavWire device and reference SpinPlus Nav device, connects with the TruDi™ Navigation System to track the EM navigable guidewire within an electromagnetic field, which displays the magnetic sensor position relative to a patient's pre-operative CT scan.

The only difference in technological characteristics between the subject TruDi™ NAV Wire device and reference SpinPlus Nav device is how the rotation of the distal region of the device is achieved. This feature is similar in the subject device and reference device and do not raise any significant issues of safety and effectiveness when used as labeled, as demonstrated by performance testing.

See Table 1 for a comparison of the technological characteristics between the subject device and the predicate/reference devices.

Attribute	Primary Predicate Device (Acclarent® NavWire)	Reference Device (Relieva SpinPlus Nav™ Balloon Sinuplasty System)	Subject Device (TruDi™ NAV Wire)
Manufacturer	Acclarent, Inc.	Acclarent, Inc.	Acclarent, Inc
510(k) Number	K161697	K171687	K190532
Proprietary Trade Name	Acclarent® NavWire Sinus Navigation Guidewire	Relieva SpinPlus Nav™ Balloon Sinuplasty System	TruDi™ NAV Wire
Common Name	Stereotaxic Instrument	Sinus Dilation System	Stereotaxic Instrument
Class	Class II	Class I	Class II
Product Code	PGW	LRC	PGW
Classification Section	21 CFR 882.4560	21 CFR 874.4420	21 CFR 882.4560
Indications for Use	The 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 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.	The RELIEVA SPINPLUS™ Nav Balloon Sinuplasty System is intended to provide a means to access the sinus space, within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures. For children aged 17 and under, the RELIEVA SPINPLUS™ Nav Balloon Sinuplasty System is intended to provide a means to access the sinus space, within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; and irrigate from within the maxillary sinus for therapeutic procedures and to facilitate diagnostic procedures.	The TruDi™ NAV Wire is intended for use as an electromagnetically navigable guidewire to provide access and confirmation of placement in the patient anatomy. The device is intended for use during ENT procedures where reference to a rigid anatomical structure can be identified relative to a CT-based model of the anatomy.

Attribute	Primary Predicate Device (Acclarent® NavWire)	Reference Device (Relieva SpinPlus Nav™ Balloon Sinuplasty System)	Subject Device (TruDi™ NAV Wire)
		The RELIEVA SPINPLUS™ Nav Balloon Sinuplasty System may be utilized in conjunction with the ACCLARENT® ENT Navigation System, to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy.	
Single-Use	Yes	Yes	Yes
Sterile	EtO Sterile	EtO Sterile	EtO Sterile
Direct Patient Contact	Yes Limited Duration < 24 hours	Yes Limited Duration < 24 hours	Yes Limited Duration < 24 hours
Labeled as Non-pyrogenic?	No	No	No
Guidewire Diameter	0.035 inches	0.035 inches	0.035 inches
Tracking Method	Electromagnetic with Magnetic Sensor at Distal Wire Tip	Electromagnetic with Magnetic Sensor at Distal Wire Tip	Electromagnetic with Magnetic Sensor at Distal Wire Tip
Flexible	Yes- flexible guidewire	Yes- flexible sinus balloon catheter and guidewire	Yes- flexible guidewire
Principle of Operation	The Acclarent® NavWire Sinus Navigation Guidewire utilizes electromagnetic image-guided sinus surgery and is 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	Combines a Sinus Guide Catheter and Handle Assembly (integrated with Sinus Balloon Catheter, Sinus Irrigation and Sinus Navigation System) into a single device. The device is connected to the TruDi™ Navigation System to provide location information via EM navigation relative to a pre-loaded scan.	The TruDi™ NAV Wire utilizes electromagnetic image-guided ENT surgery and is 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. TruDi™ NAV Wire provides real-time tracking at the distal tip of the guidewire in the nasal anatomy.

Attribute	Primary Predicate Device (Acclarent® NavWire)	Reference Device (Relieva SpinPlus Nav™ Balloon Sinuplasty System)	Subject Device (TruDi™ NAV Wire)
	at the distal tip of the guidewire in the nasal anatomy.		
Compatible devices	TruDi™ Navigation System and UltirraNav™ Sinus Balloon Catheter	TruDi™ Navigation System	TruDi™ Navigation System and non-ferromagnetic instruments that have a lumen of greater than 1mm in diameter and a luer lock mechanism to fix the wire onto the instrument.

[807.92(b) (1)] Determination of Substantial Equivalence	
Non-Clinical Performance Data:	Bench testing has been performed and met all acceptance criteria for attributes, such as simulated use testing, dimensional specifications, insertion durability, rotational durability, suction durability, joint separation force, stiffness, swivel functional performance, frictional force, and location accuracy (sensor sensitivity). The sterilization process has been validated per ISO 11135:2014 and demonstrated a sterility assurance level of 10^{-6}. The method used for sterilization validation is the overkill (half-cycle approach) in a fixed chamber. Ethylene oxide residuals have been tested and meet ISO 10993-7:2008 requirements. The subject device is not tested nor labeled as "non-pyrogenic". Biocompatibility testing was successfully completed to determine that the TruDi™ NAV Wire is biocompatible per ISO 10993-1. Packaging shelf life for the TruDi™ NAV Wire was established through accelerated aging via ASTM F1980-07, ASTM F88/F88M-09, and ASTM F2096-11 requirements and confirmed to meet a shelf life of three months. The TruDi™ NAV Wire passed all intended criteria in accordance with appropriate test criteria and standards.
[807.92(b) (2)] Determination of Substantial Equivalence	
Clinical Performance Data	Clinical data was not necessary for the TruDi™ NAV Wire. The performance data demonstrated that the device performs as intended.
[807.92(b) (3)] Conclusion	
Conclusion from Non-Clinical and Clinical Tests	Based on the information provided in this premarket notification, Acclarent concludes that the TruDi™ NAV Wire is as safe and effective and substantially equivalent to the predicate device.