July 20, 2018

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

Re: K180948
Trade/Device Name: TruDi™ NAV Suction Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: June 21, 2018
Received: June 22, 2018

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. 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.

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 yours,

Srinivas Nandkumar -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

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)*
K180948

Device Name
TruDi™ NAV Suction Instruments

Indications for Use *(Describe)*
TruDi™ NAV Suction Instruments are intended for use with the TruDi™ Navigation System during surgical procedures in ENT medicine and skull base surgery to provide navigation of the instruments to the targeted anatomy, and evacuation of gases, liquids, and fragments.

TruDi™ NAV Suction Instruments are intended to be used by ENT surgeons or support staff.

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
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Date Summary Prepared: July 18, 2018

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

Device Trade Name:	TruDi™ NAV Suction Instruments
Classification Name:	Stereotaxic Instrument
Common Name:	EM Navigable Suction Instruments
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:	KARL STORZ EM Navigated Suction Tubes, (K161555) *(cleared as part of the KARL STORZ NAV1 Electromagnetic Navigation System under K161555)*
Reference Device:	Medtronic EM ENT Navigated Suctions, (K153555)

[807.92(a)(4)] Device Description

Device Description: TruDi™ NAV Suction Instruments (0°, 70°, 90°) are electromagnetically-navigated reusable devices intended to be used in conjunction with the TruDi™ Navigation System. When used with the TruDi™ Navigation System, the TruDi™ NAV Suction Instruments provide navigation of the devices to targeted anatomy and evacuate gases, liquids, and fragments. The TruDi™ Navigation System is the trade name for the ACCLARENT® ENT Navigation System cleared in K173628.

TruDi™ NAV Suction Instrument Set consists a 0° suction instrument, 70° suction instrument, 90° suction instrument, and a single-use sterile cable called the TruDi™ NAV Cable. The TruDi™ NAV Cable may be used to connect the suction instruments to the TruDi™ Navigation System.

The TruDi™ NAV Suction Instruments include an EM trackable single axis sensor, which is integrated at the distal tip of the device. The TruDi™ Navigation System acquires the position and orientation of the distal tip of the device and displays it in real-time view over the patient's pre-operative CT scan to confirm access of target anatomy. Following confirmation, the physician operates the surgical instrument at the target anatomical structure.

[807.92(a)(5)] Intended Use

Indications for Use:	TruDi™ NAV Suction Instruments are intended for use with the TruDi™ Navigation System during surgical procedures in ENT medicine and skull base surgery to provide navigation of the instruments to the targeted anatomy, and evacuation of gases, liquids, and fragments. TruDi™ NAV Suction Instruments are intended to be used by ENT surgeons or support staff.
Difference in Indications from Predicate Device	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:	See Table 1 for a comparison of the technological characteristics between the subject device and the predicate/reference devices.

Table 1: Comparison of Technological Characteristics between ACCLARENT® Navigable Suction Instruments and Predicate and Reference devices.

Attribute	Predicate Device (KARL STORZ EM Navigated Suction Tubes)	Reference Device (Medtronic EM ENT Navigated Suctions)	Subject Device (TruDi™ NAV Suction Instruments)
510(k) number	K161555	K153555	K180948
Manufacturer	KARL STORZ Endoscopy America, Inc.	Medtronic Navigation, Inc.	Acclarent, Inc.
Trade Name	KARL STORZ EM Navigated Suction Tubes (Cleared as part of KARL STORZ NAV1 Electromagnetic Navigation System under K161555)	Medtronic EM ENT Navigated Suctions	TruDi™ NAV Suction Instruments
Classification Name	Stereotaxic Instrument	Stereotaxic Instrument	Stereotaxic Instrument
Class	II	II	II
Product Code	PGW	PGW	PGW
Classification Section	21 CFR 882.4560	21 CFR 882.4560	21 CFR 882.4560

Attribute	Predicate Device (KARL STORZ EM Navigated Suction Tubes)	Reference Device (Medtronic EM ENT Navigated Suctions)	Subject Device (TruDi™ NAV Suction Instruments)
Indications for Use	The KARL STORZ NAV1 electromagnetic navigation system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures under visual control. Their use is indicated for any medical condition in which use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as paranasal sinuses, mastoid anatomy, can be identified relative to radiological image data or digitized landmarks of the anatomy.	EM ENT Instruments are indicated for use in navigated ENT procedures to locate points on patient anatomy relative to a CT-based or MR-based digital model and to remove fluids, semi-fluid substances, tissue, and bone dust. EM ENT Instruments are indicated for use with Medtronic computer-assisted surgery systems. The EM ENT instruments are indicated for use in ENT procedures such as: • CSF leak repairs related to ENT procedure • Intranasal procedures • Orbital decompression procedures • Polyposis procedures • Endoscopic dacryocystorhinostomy • Sinus procedures, such as maxillary antrostomies • Ethmoidectomies •Sphenoidotomies/sphenoid explorations • Turbinate resections and frontal sinusotomies The EM ENT instruments can also be used in the ENT surgical approach for the following procedures: • Pituitary tumor removal • Skull base procedures • Transsphenoidal procedures • Optic nerve decompression procedures • Encephalocele procedures	TruDi™ NAV Suction Instruments are intended for use with the TruDi™ Navigation System during surgical procedures in ENT medicine and skull base surgery to provide navigation of the instruments to the targeted anatomy, and evacuation of gases, liquids, and fragments. TruDi™ NAV Suction Instruments are intended to be used by ENT surgeons or support staff.

Attribute	Predicate Device (KARL STORZ EM Navigated Suction Tubes)	Reference Device (Medtronic EM ENT Navigated Suctions)	Subject Device (TruDi™ NAV Suction Instruments)
Intended Use	The navigated suction tubes aid orientation and the suctioning of gases, liquids, and fragments during invasive interventions in ENT medicine and lateral skull base surgery not involving contact with the central nervous system.	The Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where MR-based model, or digitized landmarks of the anatomy. The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgement.	TruDi™ NAV Suction Instruments are intended for use with the TruDi™ Navigation System during surgical procedures in ENT medicine and skull base surgery to provide navigation of the instruments to the targeted anatomy, and evacuation of gases, liquids, and fragments. TruDi™ NAV Suction Instruments are intended to be used by ENT surgeons or support staff.

Attribute	Predicate Device (KARL STORZ EM Navigated Suction Tubes)	Reference Device (Medtronic EM ENT Navigated Suctions)	Subject Device (TruDi™ NAV Suction Instruments)
Technological Characteristics	The KARL STORZ EM Navigated Suction Tubes are electromagnetically-navigated when used in conjunction with the KARL STORZ NAV1 electromagnetic navigation system. A sensor is integrated at the distal tip of the suction tubes. The location of the distal tip of the device is identified by the KARL STORZ NAV1 electromagnetic navigation system, and displayed in real-time view over the patient's pre-operative CT/MTI scan to confirm access of target anatomy. Following confirmation, the physician operates the suction instrument at the target anatomical structure.	The Medtronic EM Navigated Suction Instruments are electromagnetically-navigated when used in conjunction with the Medtronic StealthStation® System System. The EM ENT Instrument Tracker, which includes a single user sensor, is attached to the EM ENT navigated suction to track its position. The location of the instrument tracker is identified by the Medtronic StealthStation® System, and displayed in real-time view over the patient's pre-operative CT/MRI scan to confirm access of target anatomy. Following confirmation, the physician operates the surgical instrument at the target anatomical structure. Following confirmation, the physician operates the suction instrument at the target anatomical structure.	TruDi™ NAV Suction Instruments are electromagnetically-navigated when used in conjunction with the TruDi™ Navigation System. A single-axial sensor (SAS) is integrated into the distal tip of the suction instruments. The location of the distal tip of the device is identified by the TruDi™ Navigation System electromagnetic navigation system, and displayed in real-time view over the patient's pre-operative CT scan to confirm access of target anatomy. Following confirmation, the physician operates the suction instrument at the target anatomical structure.
Localization Technology	Electromagnetic (sensor integrated into distal tip of suction instrument)	Electromagnetic (proximal tracker attached to suction instrument)	Electromagnetic (sensor integrated into distal tip of suction instrument)
System or Instrument Accuracy Requirements	Unknown	**EM ENT Navigated Suctions** Within a standard controlled environment: navigated peg errors of 1.54 mm at 95% confidence and 99% reliability Within a simulated surgical environment: navigated peg errors of 1.73 mm at 5% confidence and 99% reliability	≤ 2mm RMS over the entire navigation volume

Attribute	Predicate Device (KARL STORZ EM Navigated Suction Tubes)	Reference Device (Medtronic EM ENT Navigated Suctions)	Subject Device (TruDi™ NAV Suction Instruments)
Suction Functionality	Yes	Yes	Yes
Rigid Suction Device	Yes	Yes	Yes
Instrument Tip Configurations	Standard (straight) Olive	Standard (straight) Angle Olive Ball/Angle	Standard (straight) Olive
Materials	**EM ENT Navigated Suction Tubes:** Stainless Steel **Cable** Unknown	**EM ENT Navigated Suctions** Stainless Steel, Titanium **Patient and Instrument Trackers** Patient contacting cable: AES Santoprene® 8281-90 material with Colorant Pantone 301C	**TruDi™ NAV Suction Instruments** Stainless Steel 316L **TruDi™ NAV Cable** Polycarbonate, Polyvinyl Chloride (PVC), copper
Instrument Shaft Configurations	Straight 0° & Curved (~70°)	Fixed- Straight, Small Straight, 45° frontal, 70° curve, 90° curve, 90° frontal	Straight 0°, 70° curve, 90° curve
Supplied as "Reusable Use"	**EM ENT Navigated Suction Tubes:** Yes **Cable:** Yes (attached to the Suction Tubes)	**EM ENT Navigated Suctions** Yes **Patient and Instrument Trackers** Supplied Sterile Single Use	**TruDi™ NAV Suction Instruments** Yes **TruDi™ NAV Cable** Supplied Sterile Single Use
Location of Sensor	Sensor is built-in at the distal tip of the suction tube	Single-use sensor that is clipped onto the suction instrument	Sensor is built-in at the distal tip of suction instrument
Reprocessing methods	Manual Cleaning, Steam Sterilization, STERRAD® 100NX® Standard sterilization cycle, and V-PRO® 1 Plus Lumen sterilization cycle	Manual Cleaning & Steam Sterilization	Manual Cleaning, Automated Cleaning, Steam Sterilization (autoclave) & STERRAD
Compatible Navigation System	KARL STORZ EM Navigated Suction Tubes are compatible with KARL STORZ NAV1 Electromagnetic Navigation System	Medtronic EM ENT Navigated Suctions are compatible with Medtronic StealthStation® System	TruDi™ NAV Suction Instruments are electromagnetically-navigated when used in conjunction with the TruDi™ Navigation System

[807.92(b) (1)] Determination of Substantial Equivalence

Non-Clinical Performance Data:

TruDi™ NAV Suction Instruments met all performance acceptance criteria including dimensional specifications, suction flow performance, deflection, location accuracy (sensor sensitivity), reprocessing reliability, electrical functionality, and EEPROM verification.

TruDi™ NAV Suction Instruments are supplied non-sterile; they must be cleaned and sterilized prior to the initial use and before each subsequent use. Reprocessing and sterilization testing was conducted and met all acceptance criteria. When used in accordance with the Instructions for Use, the TruDi™ NAV Suction Instruments may be thoroughly cleaned and sterilized using, a combination of manual or automated cleaning methods, and steam or STERRAD sterilization. The TruDi™ NAV Cable is provided sterile and is for single use.

The sterilization process has been validated per AAMI/ANSI/ISO 11135:2014 and demonstrated a sterility assurance level of 10^{-6} when the device is sterilized via either steam or STERRAD methods. The method used for steam and STERRAD sterilization validation was overkill (half-cycle approach) in a fixed chamber.

Biocompatibility testing was successfully completed to determine that the TruDi™ NAV Suction Instruments are biocompatible per ISO 10993-1.

Simulated use testing was performed with ENT surgeons and support staff, which successfully tested the mechanical aspects, suction performance, clinical accuracy of the subject device, along with the functionality of the TruDi™ NAV cable. The packaging and instructions for use were also successfully assessed by evaluators as part of the study. The testing demonstrated that the subject device functions in accordance with design specifications and intended use. Clinical data was not necessary for the TruDi™ NAV Suction Instruments

Testing was performed to verify the navigation accuracy of the subject device when used with the TruDi™ Navigation System (K173628). Testing included sensitivity and connectivity verification.
The performance data demonstrated that the device performs as intended.

Packaging shelf life for the TruDi™ NAV Cable was established through accelerated aging via ASTM F1980-07, ASTM F88/F88M-09, and ASTM F2096-04 requirements and confirmed to meet a shelf life of two months.

[807.92(b) (2)] Determination of Substantial Equivalence	
Clinical Performance Data	Clinical data was not necessary for the TruDi™ NAV Suction Instruments. 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 Suction Instruments are safe and effective and substantially equivalent to the predicate and reference devices.