August 12, 2020

Acclarent, Inc.
Leena Sorathia
Regulatory Affairs Program Lead
31 Technology Drive
Irvine, California 92618

Re: K201174
Trade/Device Name: TruDi Curette
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: July 14, 2020
Received: July 16, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 J. 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)*
K201174

Device Name
TruDi™ Curette

Indications for Use *(Describe)*
TruDi™ Curette is intended for use with the TruDi™ Navigation System to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery.

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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K201174 - 510(K) SUMMARY

[807.92(a)(1)] Submitter Information

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

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

Date Summary Prepared: July 14, 2020

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

Device Trade Name:	TruDi™ Curette
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: KARL STORZ EM Frontal Sinus Curette
(Cleared as part of KARL STORZ NAV1 Electromagnetic Navigation System under K161555)

Reference Device: TruDi™ Probe (K193453)

[807.92(a)(4)] Device Description

Device Description: The subject device, TruDi™ Curette (K201174), is a single-use and sterile electromagnetically (EM) navigated instrument, which is intended for use with the TruDi™ Navigation System (K192397) to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery.

The TruDi™ Curette consists of one configuration (straight 0°). The TruDi™ Curette comprises of a fixed proximal connector, cable, handle, stainless steel

shaft, and a curette cup, which is located at the distal tip and houses a magnetic sensor. The device is sold in sterile packaging. Each package includes one TruDi™ Curette in conjunction with a disposable bending tool. The bending tool is provided to allow the user to customize the shape of the distal shaft as needed.

The TruDi™ Curette incorporates a sensor at the distal tip, which is tracked by the TruDi™ Navigation System. The location of the distal tip of the device is identified by the navigation system and displayed in real-time view over the patient's pre-operative CT/MRI scan to confirm access, and to locate anatomical structures during ENT and ENT skull base surgery.

[807.92(a)(5)] Intended Use

Indications for Use:	TruDi™ Curette is intended for use with the TruDi™ Navigation System to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery.
Difference in Indications from Predicate Device	The indications for use/intended use statement of the subject device is similar to the predicate device. Both the subject and predicate devices are electromagnetically-navigated instruments, which are intended to be used with their compatible EM navigation systems to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery. For a comparison of the indications for use/intended use of the subject device and its predicate device, please reference Table 1 on the following page.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:	The TruDi™ Curette is substantially equivalent in technological characteristics, as there are no significant differences in fundamental scientific technology or other features as compared to the predicate device, KARL STORZ EM Frontal Sinus Curette (K161555) and reference device, TruDi™ Probe (K193453). Both the subject and predicate devices are electromagnetically-navigated instruments, which are intended to be used with their compatible EM navigation systems to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery. Similar to the predicate device, the subject device incorporates a sensor within the distal shaft, which is tracked by the navigation system. The location of the distal tip of the device is identified by the navigation system and displayed in real-time view over the patient's pre-operative CT/MRI scan to confirm access, and to locate anatomical structures during ENT and ENT skull base surgery. The primary differences between the subject and predicate device are the following: • The subject device is a single-use instrument, whereas the predicate device is reusable for up to 30 uses.

- The subject device is packaged with a bending tool, whereas the predicate device is not.
- The subject device consists of one configuration (straight 0°), whereas the predicate devices consists of two configurations (curved 55°and 90°).
- The distal shaft of the subject device is malleable and can be formed with the provided bending tool per physicians' preference, whereas the predicate device has a rigid distal shaft.
- The sensor in both the subject and predicate devices are located within the distal shaft of the devices. While the sensor in the subject device is located ~1cm away from the distal tip, the sensor in the predicate device is located ~6cm away from the distal tip.
- The total length of the subject device is 24cm, whereas the total length of the predicate device is 18cm.
- The handle construction of subject device consists of polycarbonate material, whereas the predicate device handle consists of stainless steel.

However, these differences do not raise new concerns of safety and effectiveness for the subject device as demonstrated by performance testing and design validation testing (simulated use testing).

Additionally, the technological characteristics of the subject device are similar to the reference device. The subject device utilizes identical sensor subassembly (sensor, wire, PCB, and connector) and navigation platform as the reference device. Similar to the reference device, the sensor of the subject device is located at the distal tip for instrument tracking. 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 Subject Device and Predicate/Reference Devices

Attribute	Predicate Device KARL STORZ EM Frontal Sinus Curette	Reference Device TruDi™ Probe	Subject Device TruDi™ Curette	Substantial Equivalence Rationale
510(k) number	K161555	K193453	K201174	N/A
Manufacturer	KARL STORZ Endoscopy America, Inc.	Acclarent, Inc.	Acclarent, Inc.	N/A
Trade Name	KARL STORZ EM Frontal Sinus Curette (Cleared as part of KARL STORZ NAV1 Electromagnetic Navigation System under K161555)	TruDi™ Probe	TruDi™ Curette	N/A
Classification Name	Stereotaxic Instrument	Stereotaxic Instrument	Stereotaxic Instrument	Same
Class	II	II	II	Same
Product Code	PGW	PGW	PGW	Same
Classification Section	21 CFR 882.4560	21 CFR 882.4560	21 CFR 882.4560	Same
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.	The TruDi™ Probe is intended for use with the TruDi™ Navigation System to locate anatomical structures during surgical procedures in ENT and ENT skull base surgery.	TruDi™ Curette is intended for use with the TruDi™ Navigation System to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery.	The indications for use for the subject device TruDi™ Curette is aligned with the indications for use/intended use of the predicate device.

Attribute	Predicate Device KARL STORZ EM Frontal Sinus Curette	Reference Device TruDi™ Probe	Subject Device TruDi™ Curette	Substantial Equivalence Rationale
Intended Use	Navigated spoons and curettes aid orientation and the manipulation, dissection and/or removal of tissue, cartilage and bone during invasive and surgically invasive interventions in ENT medicine and skull base surgery not involving contact with the central nervous system.	The TruDi™ Probe is intended for use with the TruDi™ Navigation System to locate anatomical structures during surgical procedures in ENT and ENT skull base surgery.	TruDi™ Curette is intended for use with the TruDi™ Navigation System to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery.	The intended use for the subject device TruDi™ Curette is aligned with the intended use of the predicate device.
Technological Characteristics	The KARL STORZ EM Frontal Sinus Curette is a reusable electromagnetically-navigated instrument, which is intended to be used with the KARL STORZ NAV1 electromagnetic navigation system. The device incorporates a sensor within the distal shaft, which is tracked by the navigation system. The location of the distal tip of the device is identified by the navigation 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 instrument at the target anatomical structure.	The TruDi™ Probe is a single-use instrument intended to be used with the TruDi™ Navigation System. The instrument is an electromagnetically navigated device that is a navigated pointing device (malleable, sensor within the tip). The device incorporates a sensor at the distal tip, which is tracked by the TruDi™ Navigation System. The location of the distal tip of the device is identified by the navigation system and displayed in real-time view over the patient's pre-operative CT/MRI scan to confirm access and locate anatomical structures during ENT surgery.	The TruDi™ Curette is a single-use electromagnetically-navigated instrument, which is intended to be used with the TruDi™ Navigation System. The device incorporates a sensor within the distal shaft, which is tracked by the TruDi™ Navigation System. The location of the distal tip of the device is identified by the navigation 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 instrument at the target anatomical structure.	The technological characteristics between the subject device and predicate/reference devices are similar. Both the subject and predicate devices are electromagnetically-navigated instruments, which are intended to be used with their compatible EM navigation systems to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery. Similar to the predicate device, the subject device incorporates a sensor within the distal shaft, which is tracked by the navigation system. The subject device utilizes identical sensor subassembly (sensor, wire, PCB, and connector) and navigation platform as the reference device. Similar to the reference device, the sensor of the subject device is located at the distal tip for instrument tracking.

Attribute	Predicate Device KARL STORZ EM Frontal Sinus Curette	Reference Device TruDi™ Probe	Subject Device TruDi™ Curette	Substantial Equivalence Rationale
Localization Technology	Electromagnetic (sensor integrated within the distal shaft of the instrument)	Electromagnetic (sensor integrated into distal tip of the instrument)	Electromagnetic (sensor integrated within the distal shaft of the instrument)	Same
Location Accuracy	Unknown	The accuracy of TruDi™ Probe used in conjunction with the navigation views of the TruDi™ Navigation System is ≤ 2mm RMS over the entire navigation volume.	The accuracy of TruDi™ Curette used in conjunction with the navigation views of the TruDi™ Navigation System is ≤ 2mm RMS over the entire navigation volume.	Location accuracy specifications are identical between the subject and reference devices.
Instrument Shaft Configurations	Curved (55°), Curved (90°)	Straight (0°), Frontal (70°)	Straight (0°)	The subject device is packaged with a bending tool to allow the user to customize the distal shaft of the device to surgical profiles ranging from a straight configuration to curved 90°. This range also includes curved 65°. Additionally, the IFU includes detailed instructions on how to bend the distal shaft per the user's preference. The clinical acceptability of the bending process has been successfully validated as part of the design validation testing.

Attribute	Predicate Device KARL STORZ EM Frontal Sinus Curette	Reference Device TruDi™ Probe	Subject Device TruDi™ Curette	Substantial Equivalence Rationale
Total Length	18cm	24 cm	24cm	The total length specifications are identical between the subject and reference devices. The difference in total length between the subject and predicate devices is driven by the differences in the length of the handle and working length of the devices. The working length of the predicate device is 7.6 cm as opposed to working length of the subject device at 12.7 cm. The handle length of the subject device is 11.4 cm while handle length of the predicate device is 10.2 cm. The difference in the working length of the predicate and subject devices is based on several Voice of Customer (VOC) activities and has been successfully validated during design validation testing. This difference improves usability of the subject device and does not introduce any additional risks. The differences between the handles of the subject and predicate devices are based on guidelines of ANSI/AAMI/HE75:2009/ (R)2018 to enhance human factors characteristics

Attribute	Predicate Device KARL STORZ EM Frontal Sinus Curette	Reference Device TruDi™ Probe	Subject Device TruDi™ Curette	Substantial Equivalence Rationale
				of the subject device. The handle of the subject device is identical to handle of the reference device and has been successfully validated during design validation testing.
Supplied as "Reusable Use"	Yes, 30x reusable	No, supplied sterile single use	No, supplied sterile single use	Both the subject and references devices are supplied single use and subjected to identical sterilization processes.
Compatible Navigation System	KARL STORZ EM Frontal Sinus Curette is compatible with the KARL STORZ NAV1 Electromagnetic Navigation System.	TruDi™ Probe is compatible with the TruDi™ Navigation System versions V2.0 or later	TruDi™ Curette is compatible with the TruDi™ Navigation System versions V2.0 or later	Both the subject and references devices are compatible with the TruDi™ Navigation System versions V2.0 or later. All functional and simulated use testing has been performed with the TruDi™ Navigation System. As such, the subject device is only compatible with the TruDi™ Navigation System.

[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 dimensional specifications, connector joint separation force, distal shaft deflection/flexure, end to end joint strength, cable strain relief separation force, tip sharpness, bending tool functionality and navigational location accuracy. Electrical safety and EMC tests were performed by a nationally recognized testing laboratory to verify compliance with the requirements of IEC 60601-1 (3rd Edition) and IEC60601-1-2 (4th Edition). 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™ Curette is biocompatible per ISO 10993-1. Packaging shelf life for the TruDi™ Curette 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. Design validation testing (simulated use testing) on cadavers was successfully conducted to verify that the TruDi™ Curette functions in accordance with its intended use and design specifications in a simulated clinical setting. The packaging and instructions for use were also successfully assessed by evaluators as part of the study. The TruDi™ Curette 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™ Curette. 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™ Curette is substantially equivalent to the predicate device.