March 23, 2020

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

Re: K193453
Trade/Device Name: TruDi Probe
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: PGW
Dated: March 3, 2020
Received: March 4, 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)*
K193453

Device Name
TruDi™ Probe

Indications for Use *(Describe)*
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.

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.
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: March 20, 2020

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

Device Trade Name:	TruDi™ Probe
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: Fiagon Navigation – FlexPointer 1.5, (K150473)

[807.92(a)(4)] Device Description

Device Description: The subject device, TruDi™ Probe, is a single-use and sterile electromagnetically (EM) navigated instrument, which is intended for use with the TruDi™ Navigation System (K192397) to locate anatomical structures during surgical procedures in ENT and ENT skull base surgery.

The TruDi™ Probe consists of two configurations, straight (0°) and frontal (70°). The TruDi™ Probe comprises of a fixed proximal connector, cable, handle, stainless steel shaft, and a distal tip that houses a magnetic sensor. The device is sold in sterile packaging. Each package includes one TruDi™ Probe (either straight or frontal) in conjunction with a disposable bending tool. The bending tool is provided to allow the user to customize the shape of distal tip as needed.

The TruDi™ Probe 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 scan to confirm access and locate anatomical structures during ENT surgery.

[807.92(a)(5)] Intended Use

Indications for Use:

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.

Difference in Indications from Predicate Device

The indications for 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 locate anatomical structures during ENT surgery.

For a comparison of the indications for 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™ Probe 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, Fiagon FlexPointer 1.5mm (K150473).

Both the subject and predicate devices are electromagnetically-navigated instruments, which are intended to be used with their compatible EM navigation systems to locate anatomical structures during ENT surgery. Similar to the predicate device, the subject device incorporates a sensor at the distal tip, 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 scan to confirm access and locate anatomical structures during ENT surgery.

The primary differences between the subject and predicate devices are the following:

- The subject device is a single-use instrument, whereas the predicate device is reusable for up to 10 uses.
- The subject device is packaged with a bending tool, whereas the predicate device is not.
- The distal tip diameter of the subject device is 1.65 mm, whereas the distal tip diameter of the predicate device is 1.5mm.
- The handle of subject device is different from the handle of predicate device in length, shape, diameter and cross-section.

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

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

Table 1: Comparison of Technological Characteristics between Subject Device and Predicate Device

Attribute	Predicate Device Fiagon FlexPointer 1.5mm	Subject Device TruDi™ Probe	Substantial Equivalence Rationale
510(k) number	K150473	K193453	N/A
Manufacturer	Fiagon GmbH	Acclarent, Inc.	N/A
Trade Name	Fiagon Navigation – FlexPointer 1.5	TruDi™ Probe	N/A
Classification Name	Stereotaxic Instrument	Stereotaxic Instrument	Same
Class	II	II	Same
Product Code	PGW	PGW	Same
Classification Section	21 CFR 882.4560	21 CFR 882.4560	Same
Indications for Use	The FlexPointer 1.5 is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. It is indicated for use with the Fiagon Navigation system using electromagnetic navigation. It is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy. Example procedures include, but are not limited to: ENT Procedures; Transphenoidal access procedures. Intranasal procedures. Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies. ENT related anterior skull base procedures.	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.	The indications for use of the subject TruDi™ Probe device is aligned with the indications for use of the predicate device.

Attribute	Predicate Device Fiagon FlexPointer 1.5mm	Subject Device TruDi™ Probe	Substantial Equivalence Rationale
Intended Use	The FlexPointer 1.5 is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. It is indicated for use with the Fiagon Navigation system using electromagnetic navigation. It is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy. Example procedures include, but are not limited to: ENT Procedures; Transphenoidal access procedures. Intranasal procedures. Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies. ENT related anterior skull base procedures.	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.	The intended use of the subject TruDi™ Probe device is aligned with the intended use of the predicate device.

Attribute	Predicate Device Fiagon FlexPointer 1.5mm	Subject Device TruDi™ Probe	Substantial Equivalence Rationale
Technological Characteristics	The Fiagon Navigation - FlexPointer 1.5 is a reusable instrument intended to be used with the Fiagon 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 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™ 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 technological characteristics have been tested through non-clinical testing and they do not impact substantial equivalence. The differences do not raise any new concerns.
Localization Technology	Electromagnetic (sensor integrated into distal tip of the instrument)	Electromagnetic (sensor integrated into distal tip of the instrument)	Same
System or Instrument Accuracy Requirements	A mean bench accuracy of 1.1 mm (Standard deviation 0.27 mm) was measured for the device. All 95% confidence levels were < 2mm which compares to the values 0.9 mm and 1.2 mm (mean) resp. <2 mm (95% confidence) reported for the unmodified devices.	A mean bench accuracy of 0.43 mm (Standard deviation 0.15 mm) was measured for the device. With 95% confidence measured devices have location accuracy of ≤ 2 mm RMS over the entire navigation volume.	The system and instrument accuracy requirements have been tested through non-clinical testing and they do not impact substantial equivalence. The differences do not raise any new concerns.
Instrument Shaft Configurations	Straight (0°)	Straight (0°), Frontal (70°)	The instrument shaft configurations have been tested through non-clinical testing and they do not impact substantial equivalence. The differences do not raise any new concerns.
Distal Tip Diameter	1.5mm	1.65mm	The distal tip diameter has been tested through non-clinical testing and does not impact substantial equivalence. The differences do not raise any new concerns.

Attribute	Predicate Device Fiagon FlexPointer 1.5mm	Subject Device TruDi™ Probe	Substantial Equivalence Rationale
Handle	Length: ~ 1 inch Shape: Rectangular profile Cross-section: Rectangular (~ 1.0 inch x 0.7 inches x 0.4 inches)	Length: 4.5 inches Shape: Cylindrical profile Cross-section: Circular Diameter: 0.45 inches	The handle design of the subject device complies with ANSI/AAMI/HE75:2009/(R)2018. Handle design features i.e. length, shape, cross-section and diameter were evaluated and verified through several VOC activities to ensure that the handle met ergonomic and functional expectations of prospective users. In addition, the clinical acceptability and functionality of the handle design were validated through design validation testing (simulated use testing). Therefore, the handle differences of the subject and predicate devices do not affect safety and effectiveness of the subject device.
Supplied as "Reusable Use"	Yes, 10x reusable	No, supplied sterile single use	This attribute has been tested through non-clinical testing and does not impact substantial equivalence. The differences do not raise any new concerns.
Location of Sensor	Sensor is built-in at the distal tip of the instrument	Sensor is built-in at the distal tip of the instrument	Same
Compatible Navigation System	Fiagon FlexPointer 1.5mm is compatible with the Fiagon Navigation system.	TruDi™ Probe is compatible with the TruDi™ Navigation System.	This attribute has been tested through non-clinical testing and does not impact substantial equivalence. The differences do not raise any new concerns.

[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, tip flexure, distal tube to handle separation force, cable strain relief separation force, 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™ Probe is biocompatible per ISO 10993-1. Packaging shelf life for the TruDi™ Probe 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. Simulated use testing on cadavers was successfully conducted to verify that the TruDi™ Probe 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™ Probe 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™ Probe. 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™ Probe is as safe and effective as the predicate device.