July 20, 2022

Acclarent, Inc.
Leena Zalavadia
Regulatory Affairs Program Lead
31 Technology Drive, Suite 200
Irvine, California 92618

Re: K221037
Trade/Device Name: TruDi Shaver Blade
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW, ERL
Dated: June 16, 2022
Received: June 17, 2022

Dear Leena Zalavadia:

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 Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221037

Device Name
TruDi® Shaver Blade

Indications for Use *(Describe)*
TruDi® Shaver Blades are intended for use with the Bien-Air S120 Shaver Handpiece and the TruDi® Navigation System to aid in the incision and removal of soft and hard tissue or bone in ENT, Maxillofacial surgery, Head and Neck and ENT skull base surgery. Their use is indicated for any medical condition in which the use of navigated surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to a CT or MR based model.

TruDi® Shaver Blades may be used in, but is not limited to, the following procedures:
- Endoscopic sinus surgery (such as ethmoidectomy, polypectomy, septoplasty)
- Drainage of mucoceles or abscesses that have extended from the paranasal sinuses and up to the dura mater
- Orbital decompression
- Any other of a number of tumors involving the lateral nasal wall, paranasal sinuses and orbit
- Access to the sphenoid sinus

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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510(K) SUMMARY- K221037

[807.92(a)(1)] Submitter Information

Sponsor/Submitter: Acclarent, Inc.
31 Technology Drive, Suite 200
Irvine, CA 92618

Contact Person: Leena Zalavadia
Regulatory Affairs Manager
Email: lsorathi@its.jnj.com
Tel: 949-923-4118

Date Summary Prepared: July 20, 2022

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

Device Trade Name:	TruDi® Shaver Blade
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
Primary Product Code:	PGW
Secondary Product Code:	ERL

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

Predicate Device: Medtronic Navigated Quadcut Blades (K130608)

Reference Devices: Bien-Air OSSEODUO S120 Shaver Handpiece
(Cleared OSSEODUO Shaver and Drill System under K083720)

TruDi® Curette (K201174)

[807.92(a)(4)] Device Description

Device Description: The subject device, TruDi® Shaver Blade, is a single-use and sterile electromagnetically (EM) navigated instrument, which is intended to be used with the Bien-Air S120 Shaver Handpiece (reference device, K083720) and the TruDi® Navigation System (K192397) to aid in the incision and removal of soft and hard tissue or bone in ENT, Maxillofacial surgery, Head and Neck and ENT skull base surgery. The device is tracked by the navigation system within the low energy magnetic field volume generated by the TruDi® Navigation System. The TruDi® Navigation System software displays the position of the shaver blade distal tip on preoperative scans (e.g. CT, MRI). The TruDi® Shaver Blade consists of several configurations ranging from straight to curved blades of different diameters.

[807.92(a)(5)] Intended Use

Indications for Use: TruDi® Shaver Blades are intended for use with the Bien-Air S120 Shaver Handpiece and the TruDi® Navigation System to aid in the incision and removal of soft and hard tissue or bone in ENT, Maxillofacial surgery, Head and Neck and ENT skull base surgery. Their use is indicated for any medical condition in which the use of navigated surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to a CT or MR based model.

TruDi® Shaver Blades may be used in, but is not limited to, the following procedures:

- Endoscopic sinus surgery (such as ethmoidectomy, polypectomy, septoplasty)
- Drainage of mucoceles or abscesses that have extended from the paranasal sinuses and up to the dura mater
- Orbital decompression
- Any other of a number of tumors involving the lateral nasal wall, paranasal sinuses and orbit
- Access to the sphenoid sinus

Difference in Indications from Predicate Device The indications for use and intended use of the subject device, TruDi® Shaver Blade, are similar to the predicate device and reference device (Bien-Air OSSEODUO S120 Shaver Handpiece). Both the subject device and predicate device are electromagnetically navigated shaver blades intended to aid in the incision and removal of soft and hard tissue or bone during head and neck and ENT surgery. One of the reference devices, Bien-Air S120 Shaver Handpiece (K083720), is intended to be used with the subject device, therefore relevant parts of the indications for use of the reference device have been added to the indications for use for the subject device.

For a comparison of the indications for use/intended use of the subject device and its predicate device, please reference Table 1.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:

The subject device, TruDi® Shaver Blade, is substantially equivalent in technological characteristics, as there are no significant differences in design, fundamental scientific technology, or other features of the device from the predicate device.

Both the subject device and predicate device (Medtronic Navigated Quadcut Blades, K130608) are electromagnetically navigated shaver blades, which are intended to aid in the incision and removal of soft and hard tissue or bone during head and neck and ENT surgery. Similar to the predicate device, the subject device incorporates a sensor, which is tracked by its navigation system. The location of the sensor 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 surgical procedures.

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

- The subject device has a sensor integrated at the distal tip of the device, whereas the predicate device has a tracker with a sensor inside mounted on the proximal end of the blade to allow for navigation during the ENT surgical procedures
- The subject device is available in a variety of blade angles, 0° (straight), 15°, 40°, and 60° angles, while the predicate device is only available in 0° (straight) angle.
- The subject device uses a different handpiece and navigation system to operate the device than the predicate device. The subject device is intended for use with the Bien-Air S120 Shaver Handpiece (K083720), OSSEODUO control unit (K083720) and TruDi® Navigation System (K192397), whereas the predicate device is intended for use with the Medtronic M4 and M5 hand piece and Medtronic's navigation system.

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

In order to operate the subject device, it must connect to the Bien-Air S120 Shaver Handpiece (K083720), which is why it was selected as the reference device. The TruDi® Curette (K201174) is also presented as a reference device due to similarities in testing methods.

Table 1: **Substantial Equivalence Table**

Attribute	Predicate Device: Medtronic Navigated Quadcut Blades	Reference Device: Bien-Air OSSEODUO S120 Shaver Handpiece	Reference Device: TruDi® Curette	Subject Device: TruDi® Shaver Blade	Substantial Equivalence Rationale
510(k) number	K130608	K083720	K201174	K221037	N/A
Manufacturer	Medtronic Navigation, Inc.	Bien-Air Surgery SA	Acclarent, Inc.	Acclarent, Inc.	N/A
Trade Name	Quadcut	OSSEODUO Shaver and Drill System	TruDi® Curette	TruDi® Shaver Blade	N/A
Classification Name	Neurological Stereotaxic Instrument	Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece	Ear, Nose, and Throat Stereotaxic Instrument	Ear, Nose, and Throat Stereotaxic Instrument	Same as the reference device (TruDi® Curette).
Class	II	II	II	II	Same
Classification Product Code	HAW	ERL	PGW	PGW	Same as reference device (TruDi® Curette).
Secondary Product Code	N/A	N/A	N/A	ERL	Same as reference device (Bien-Air OSSEODUO S120 Shaver Handpiece).
Classification Section	21 CFR 882.4560	21 CFR 874.4250	21 CFR 882.4560	21 CFR 882.4560	Same as predicate and reference device (TruDi® Curette).

Attribute	Predicate Device: Medtronic Navigated Quadcut Blades	Reference Device: Bien-Air OSSEODUO S120 Shaver Handpiece	Reference Device: TruDi® Curette	Subject Device: TruDi® Shaver Blade	Substantial Equivalence Rationale
Indications for Use	The XPS/IPC System is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery. 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. 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 judgment.	The OSSEODUO is a drill and shaver system that has been designed for drilling and shaping bone and for "the resection of soft and hard tissues as part of surgical operations in the areas of otorhinolaryngology, otoneurology, maxillofacial surgery, and head and neck surgery." The shaver handpiece S80 or S120 is designed for cutting and removal of soft and hard tissue in the fields of: - Endoscopic sinus surgery (such as ethmoidectomy, polypectomy, septoplasty) - Endoscopic dacryocystorhinostomy (DCR) - Nasopharyngeal and laryngeal prodedures (such as adenoidectomy, polypectomy, tonsillectomy) - Head and neck surgery (such as acoustic-neuroma removal, tumor removal, rhinoplasty, adipose tissue removal, plastic, reconstructive and aesthetic 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.	TruDi® Shaver Blades are intended for use with the Bien-Air S120 Shaver Handpiece and the TruDi® Navigation System to aid in the incision and removal of soft and hard tissue or bone in ENT, Maxillofacial surgery, Head and Neck and ENT skull base surgery. Their use is indicated for any medical condition in which the use of navigated surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to a CT or MR based model. TruDi® Shaver Blades may be used in, but is not limited to, the following procedures: • Endoscopic sinus surgery (such as ethmoidectomy, polypectomy, septoplasty) • Drainage of mucoceles or abscesses that have extended from the paranasal sinuses and up to the dura mater • Orbital decompression • Any other of a number of tumors involving the lateral nasal wall, paranasal sinuses and orbit • Access to the sphenoid sinus	The indications for use for the subject device is aligned with the indications for use of the predicate and reference device (Bien-Air OSSEODUO S120 Shaver Handpiece).

Attribute	Predicate Device: Medtronic Navigated Quadcut Blades	Reference Device: Bien-Air OSSEODUO S120 Shaver Handpiece	Reference Device: TruDi® Curette	Subject Device: TruDi® Shaver Blade	Substantial Equivalence Rationale
Intended Use	The Quadcut blades are intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.	The shaver handpiece S80 or S120 is designed for cutting and removal of soft and hard tissue	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.	TruDi® Shaver Blades are intended for use with the Bien-Air S120 Shaver Handpiece and the TruDi® Navigation System to aid in the incision and removal of soft and hard tissue or bone in ENT, Maxillofacial surgery, Head and Neck and ENT skull base surgery.	The intended use for the subject device is aligned with the intended use of the predicate and reference device (Bien-Air OSSEODUO S120 Shaver Handpiece).
Technological Characteristics	Quadcut is intended for attachment to the Medtronic M4 hand piece for use in conjunction with Fusion ENT software on a Medtronic computer-assisted surgery system. Each blade has a tracker mounted on it to allow for navigation during the ENT surgical procedure. The system's mobile emitter generates a low-energy magnetic field to locate the tracker mounted on the blade. Then, the software displays the location of the blade's tip within multiple patient image planes and other anatomical renderings.	The Bien-Air S120 shaver handpiece includes a micromotor, a gear set, a coupling system for shaver blades and connections for irrigation and suction. Through the control unit it can operate in oscillating modus (reversing after a user-defined number of turns in each direction) or in continuous CW and CCW rotation.	The TruDi® Curette is a single-use electro-magnetically-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 TruDi® Shaver Blade 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 of the subject device are similar to the predicate and reference devices.

Attribute	Predicate Device: Medtronic Navigated Quadcut Blades	Reference Device: Bien-Air OSSEODUO S120 Shaver Handpiece	Reference Device: TruDi® Curette	Subject Device: TruDi® Shaver Blade	Substantial Equivalence Rationale
Localization Technology	Electromagnetic	N/A	Electromagnetic	Electromagnetic	Same as predicate device and reference device (TruDi® Curette).
System Accuracy Requirement	95% confidence / 99.5% reliability, as dictated by risk analysis, of ≤ 3.00 mm.	N/A	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.	The accuracy of TruDi® Shaver Blade used in conjunction with the navigation views of the TruDi® Navigation System is ≤ 2mm RMS over the entire navigation volume.	Same as reference device (TruDi® Curette).
Materials-blades	304L stainless steel	N/A	N/A	304L stainless steel	Same as predicate device.
Blade sizes and angles	3.0 mm Straight (0°) 4.0 mm Straight (0°) 4.3 mm Straight (0°)	N/A	N/A	3.0mm Straight (0°) 4.0mm Straight (0°) 4.0mm 15° Curved 4.0mm 40° Curved 4.0mm 60° Curved	The subject device includes additional blade angles compared to the predicate device. However, this difference does not raise new concerns of safety and effectiveness for the subject device as demonstrated by performance testing and design validation testing.
Sterilization	Ethlyene Oxide sterilization	Steam Sterilization	Ethlyene Oxide sterilization	Ethlyene Oxide sterilization	Same as predicate device and reference device (TruDi® Curette).
Single use	Yes	No (reusable)	Yes	Yes	Same as predicate device and reference device (TruDi® Curette).
Compatible Navigation System	Medtronic computer-assisted surgery system - Fusion™ and StealthStation™ ENT system	N/A	TruDi® Navigation System	TruDi® Navigation System	The subject device and reference device (TruDi® Curette) connect to the same 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, electrical tests, connector joint separation force, heat shrink slip, strain relief axial force, 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}. Biocompatibility testing was successfully completed to determine that the TruDi® Shaver Blade is biocompatible per ISO 10993-1. Packaging shelf life for the TruDi® Shaver Blade was established through accelerated aging via ASTM F1980-16, ASTM F88-15, 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® Shaver Blade functions in accordance with its intended use and design specifications in a simulated clinical setting. The packaging, labeling, and instructions for use were also successfully assessed by evaluators as part of the study. The TruDi® Shaver Blade 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® Shaver Blade. 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® Shaver Blade is substantially equivalent to the predicate device.