January 30, 2020

Biosense Webster
David Locke
Manager, Regulatory Affairs
Acclarent Inc.
33 Technology Drive
Irvine, California 92618

Re: K192397
Trade/Device Name: TruDi Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: PGW
Dated: December 31, 2019
Received: January 2, 2020

Dear David Locke:

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)*
K192397

Device Name
TruDi™ Navigation System (Version 2.0)

Indications for Use *(Describe)*
The TruDi™ Navigation System is intended for use during surgical procedures in ENT and ENT skull base surgery to support navigation of instruments to targeted anatomy, where reference to rigid anatomic structure can be identified relative to a CT or MR based model.

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

Applicant: Biosense Webster, Inc.
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Date Summary Prepared: January 30, 2020

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

Device Trade Name:	TruDi™ Navigation System
Device Common Name:	Image Guided Surgery System
Device Classification:	Class II, 21 CFR 882.4560
Classification Name:	Ear, Nose, and Throat Manual Surgical Instrument (21 CFR 882.4560)
Product Code	PGW

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

Predicate Devices: Primary: Acclarent® ENT Navigation System (K173628)
Secondary: Fiagon Navigation System (K162176)

[807.92(a)(4)] Device Description

Device Description/Technological Characteristics: The TruDi™ Navigation System V2 is intended to be used during surgical procedures in ENT and ENT skull base surgery to support navigation of instruments to the targeted anatomy, where reference to a rigid anatomical structure can be identified relative to a CT or MR based model.

The TruDi™ Navigation System V2 enables ENT physicians to access sphenoid, frontal, and maxillary sinuses, as well as the skull base, by using the systems magnetic tracking technology, which is the same technology used by both of the predicate devices.

	The system incorporates a Navigation Console, Emitter Pad, Instrument Hub, Patient Tracker, Registration Probe, and Holder, Workstation and accessories. A magnetic field generated by the Emitter Ring (Field Ring) induces a current in the magnetic sensor embedded in the tip of the flexible navigated tool, which helps to accurately calculate the tool tip position. A CT image is imported and registered to the patient coordinates and a tool tip icon is displayed on top of the registered image, indicating the position of the tool in reference to the patient anatomy. A Patient Tracker is fixed to the patient forehead to compensate for the head movement during the navigation procedure.
[807.92(a)(5)] Intended Use	
Indications for Use:	The TruDi™ Navigation System is intended for use during surgical procedures in ENT and ENT skull base surgery to support navigation of instruments to targeted anatomy, where reference to rigid anatomic structure can be identified relative to a CT or MR based model.
Predicate Comparison	
Predicate Comparison Table and Overview:	The substantial equivalence of the TruDi™ Navigation System V2 to the predicate devices is shown by similarity in intended use, indications for use, and performance. Like the predicate devices, the TruDi™ Navigation System V2 is an image-guided navigation system designed for use during ENT and ENT skull base surgical procedures. ENT physicians can track and display the real-time location of the tip of navigated instruments relative to pre-acquired CT/MR images. Additionally, like the predicate devices, the subject system utilizes electromagnetic tracking technology for navigation, uses anatomical reference points on the patient's anatomy for intraoperative registration to the image-based model of the anatomy, and uses CT/MR image sets as reference images for the image-based model. The predicate ENT Navigation systems support substantial equivalence and the differences between the subject device and the predicate devices do not raise any new questions with respect to safety and effectiveness. The table below provides a comparison of the technological characteristics between the subject device and the predicate devices.

Subject and Predicate Device Comparison Table				
Attribute	**Secondary Predicate Device Fiagon® Navigation System**	**Primary Predicate Device Acclarent® ENT Navigation System**	**Subject Device TruDi™ Navigation System V2**	**Substantial Equivalence Rationale**
510(k) Number	K162176	K173628	K192397	N/A
Physical Manufacturer	Fiagon GmbH	Biosense Webster (Israel) Ltd.	Biosense Webster (Israel) Ltd.	N/A
Distributer	Fiagon GmbH	Acclarent Inc.	Acclarent Inc.	N/A
Trade Name	Fiagon Navigation System	Acclarent® ENT Navigation System	TruDi™ Navigation System	N/A
Common Name	Image guided surgery system	Image Guided Surgery System	Image Guided Surgery System	Same
Class	Class II	Class II	Class II	Same
Product Code	PGW	PGW	PGW	Same
Classification Section	CFR 882.4560	CFR 882.4560	CFR 882.4560	Same
Indications for Use (IFU)	The Fiagon Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Fiagon Navigation System 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	The ACCLARENT® ENT Navigation System is intended for use during intranasal and paranasal image-guided navigation procedures for patients who are eligible for sinus procedures.	The TruDi™ Navigation System is intended for use during surgical procedures in ENT and ENT skull base surgery to support navigation of instruments to targeted anatomy, where reference to a rigid anatomical structure can be identified relative to a CT or MR based model.	The IFU of the subject TruDi™ Navigation System V2 device is aligned with the IFU of the secondary Predicate and is an expansion of the IFU of the primary

	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			predicate (additional anatomical sites). The expansions in the IFU are supported by the bench testing.
Fundamental Scientific Technology	Electromagnetic location	Electromagnetic location	Electromagnetic location	Same
Principles of Operation	Electromagnetic triangulation and Image registration.	Electromagnetic triangulation and Image registration.	Electromagnetic triangulation and Image registration.	Same
Technological Characteristics	Radiation of low intensity electromagnetic field. Acquisition of magnetic sensor induced voltages. Electromagnetic location in reference to registered CT/MR background of patient head.	Radiation of low intensity electromagnetic field. Acquisition of magnetic sensor induced voltages. Electromagnetic location in reference to registered CT background of patient head.	Radiation of low intensity electromagnetic field. Acquisition of magnetic sensor induced voltages. Electromagnetic location in reference to registered CT/MR background of patient head.	The technological characteristics have been tested through the non-clinical testing and they do not impact substantial equivalence. The differences do not raise any new concerns.
Control Mechanism	Software controlled	Software controlled	Software controlled	Same
Single Patient Use	No	No	No	Same
Reusable	Yes	Yes	Yes	Same
Bench Location Accuracy	0.9 mm (Standard deviation 0.34 mm)	0.55mm (standard Deviation 0.7 mm)	0.55mm (standard Deviation 0.7 mm)	The bench location accuracy has been tested through the

				non-clinical testing and the differences do not impact substantial equivalence, nor do they raise any new concerns.
Simulated Use Location Accuracy	1.79 mm (Standard deviation 0.4 mm)	0.63 mm (Standard deviation 0.2 mm)	1.1 mm (Standard deviation 0.2 mm)	The simulated use location accuracy has been tested through the non-clinical testing and the differences do not impact substantial equivalence, nor do they raise any new concerns.
Main Feature	Displays the instruments position in relation to preoperative scans utilizing electromagnetic tracking technology.	Displays the instruments position in relation to preoperative scans utilizing electromagnetic tracking technology.	Displays the instruments position in relation to preoperative scans utilizing electromagnetic tracking technology.	Same
Intended Use	Intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures.	Intended as an aid for precisely locating anatomical structures in ENT procedures.	Intended as an aid for precisely locating anatomical structures in ENT and ENT skull base procedures.	Minor differences*
Location Update Rate	15 to 45Hz	10Hz	10Hz	The location update rate has been tested through the non-clinical

				testing and the differences do not impact substantial equivalence, nor do they raise any new concerns.
Main Components	1. Navigation unit with navigation software with interface to screen mouse and items 2-4. 2. Head rest with field generator 3. Navigation instrument 4. Patient reference localizer (with fixation material)	1. Navigation unit with navigation software, with interface to 2-7 2. Field Ring 3. Patient tracker 4. Registration Probe 5. Instrument Hub 6. Isolation Transformer 7. Mouse and Keyboard	1. Navigation unit with navigation software, with interface to 2-7 2. Emitter Pad 3. Patient tracker 4. Registration Probe 5. Instrument Hub 6. Isolation Transformer 7. Mouse and Keyboard	Minor differences*
Supported Navigation Instruments	Flexible tip instruments with magnetic sensor on instrument tip	Flexible tip instruments with magnetic sensor on instrument tip	Flexible tip instruments with magnetic sensor on instrument tip	Same
Registration Tools	Registration pointer	Registration probe, manual acquisition of anatomic points and surfaces	Registration pointer	Minor differences*
Supported Preoperative Images	DICOM CT, CBCT, MR	DICOM CT	DICOM CT, MR	Minor differences*
Supported Import Media	CD-ROM, USB flash drive, LAN network	USB flash drive and CD/DVD Media	CD-ROM, USB flash drive, LAN network	The additional supported import media (LAN network) does not raise new concern (shown

				through non-clinical testing).
Packaging	Provided, non-sterile	Provided, non-sterile	Provided, non-sterile	Same
Accessory Devices Packed with Device	Yes	Yes	Yes	Same
Anatomical Site	ENT anatomy including skull base	ENT anatomy	ENT anatomy including ENT skull base	The differences in anatomical sites were shown to be substantially equivalent (through the non-clinical testing) and they do not raise any new concerns.
*Minor differences do not impact substantial equivalence and do not raise new concerns with respect to safety and effectiveness.				

Non-clinical Performance Data:

The TruDi™ Navigation System V2 was tested to ensure that it functions in accordance with the system design specifications related to substantial equivalence in terms of device safety and effectiveness.

The following nonclinical tests were performed:

1. Proof of Design electrical tests, to verify all hardware modules perform within specifications.
2. Location Accuracy tests, where the TruDi™ Navigation System electromagnetic locations were compared to the locations provided by a highly accurate robot system over the entire navigation volume to verify the system precision claim.
3. Software functional tests, covering the complete system functionality, and including error handling, usability and time performance (latency).
4. Safety, EMC, and mechanical tests were performed by a nationally recognized testing laboratory to verify compliance with safety and EMC standards for medical devices.
5. Simulated use accuracy test, in which a complete CT image registration and instrument navigation workflow was performed to verify the overall accuracy of the system.

6. Pre-clinical (cadaver) tests were designed to mimic surgical procedures using the TruDi™ Navigation System V2 in a simulated clinical environment to assess the execution of a complete sinuplasty procedure, workflow and to qualitatively estimate the systems clinical accuracy.
7. System accuracy was tested confirming that it is within 2mm and instrument angular accuracy was tested confirming that it is within 6°.
8. The Robot system (angular accuracy of 1°) used to validate system accuracy, verifies its real location based on electromagnetic field location.

The proposed TruDi™ Navigation System V2 passed all tests in accordance with appropriate test criteria and standards, and the modified device did not raise new questions of safety or effectiveness.

Clinical Performance Data: Clinical data was not necessary to determine that the subject TruDi™ Navigation System V2 performs as intended.

Conclusion: The modified TruDi™ Navigation System V2 is substantially equivalent to the currently cleared predicate devices based on the completion of non-clinical bench testing as well as similar principles of design, operation and indications for use.