July 21, 2023

Acclarent, Inc.
% Dikla Dayan
Regulatory Affairs Manager
Biosense Webster (Israel) Ltd.
4 Hatnufa St
Yokneam, 2066717
Israel

Re: K231862
Trade/Device Name: TruDi® Navigation System V3
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: June 23, 2023
Received: June 23, 2023

Dear Dikla Dayan:

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,

Joyce C. Lin -S

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)*
K231862

Device Name
TruDi® Navigation System V3

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 a rigid anatomical 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 - K231862

[807.92(a)(1)] Submitter Information	
Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite200 Irvine, CA 92618, USA Tel.: 419-233-2611 Fax: 949-450-6886
Contact person:	Kamrie Sarnosky Senior Regulatory Specialist Acclarent, Inc.
Authored by:	Dikla Dayan RA Manager Biosense Webster (Israel) Ltd
Date summary prepared:	June 23, 2023
807.92(a)(2)] Name of Device	
Device Trade Name	TruDi® Navigation System V3
Device Common Name	Image Guided Surgery System
Device Classification	Class II, 21 CFR 882.4560 Ear, Nose, and Throat Manual Surgical Instrument (21 CFR 882.4560)
Product Code	PGW
[807.92(a)(3)] Legally Marketed Devices	
Predicate Device:	TruDi® Navigation System V2 (K192397)
[807.92(a)(4)] Device Description	
Device Description:	The TruDi® Navigation System V3 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 V3 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 the predicate device. The system incorporates a Navigation Console, Emitter Pad, Instrument Hub, Patient Tracker, Registration Probe, Workstation and peripherals. A magnetic field generated by the Emitter Pad induces a current in the magnetic sensor embedded in the tip of the navigated tool, which helps to accurately calculate the tool tip position. A CT or MR image is imported and registered to the patient coordinates and the navigated tool tip icon is displayed on top of the registered image, indicating the position of the tool tip in reference to the patient anatomy. A Patient Tracker is fixed to the patient forehead to compensate for the head movement during the surgical procedure.

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[807.92(a)(5)] Intended Use

Intended use

The TruDi® Navigation System V3 is intended for use during surgical procedures in ENT and skull based 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.

Difference in Indications from Predicate Device:

There is no difference in intended use between the subject device and predicate device.

[807.92(a)(6)] Technical Characteristics

Predicate overview and comparison table:

The substantial equivalence of the TruDi® Navigation System V3 to the predicate is shown by similarity in intended use, indications for use, technology, and performance.

The TruDi® Navigation System V3 is an image-guided navigation system designed for use during ENT and skull based 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. Like the predicate device, 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 table below provides a comparison of the technological characteristics between the subject device and the predicate device.

Attributes	PREDICATE DEVICE: TRUDI NAVIGATION SYSTEM V 2.0	SUBJECT DEVICE: TRUDI NAVIGATION SYSTEM V 3.0
Fundamental Scientific Technology	Electromagnetic location	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	Same
Technology	Software embedded device	Same
Platform	PC Based	Same
Operating System	Windows 10 (64 bits)	Same
Programming Languages	Visual C++, C# and C, MATLAB, HTML	Same
Accuracy specification	2mm RMS	Same
Bench Location Accuracy	0.55mm (standard Deviation 0.7 mm)	0.55 (STD 0.2)
Simulated Use Location Accuracy	1.1 mm (Standard deviation 0.2 mm)	1.2 mm (Standard deviation 0.2mm)

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Attributes	PREDICATE DEVICE: TRUDI NAVIGATION SYSTEM V 2.0	SUBJECT DEVICE: TRUDI NAVIGATION SYSTEM V 3.0
Main Feature	Displays the instruments position in relation to preoperative scans utilizing electromagnetic tracking technology.	Same
Location Update Rate	10Hz	Same
Supported Navigation Instruments	Flexible and Rigid instruments with magnetic sensor on instrument tip	Same
Supported Preoperative Images	DICOM CT, MR	Same
Supported CT/MR Import Media	CD-ROM, USB flash drive, LAN network (PACs)	Same
Patient Data Archiving	Not supported	Supported in local disk, flash memory and hospital network PACS (new Software Function)
Packaging	Provided non-sterile	Same
HW Main components		
Instrument Hub	Enables the user to connect components and navigated tool to the system	Added connection flexibility. Verification testing has demonstrated that this change does not raise new questions on the safety and effectiveness of the device.
Workstation	Dell 5810 or Dell5820 Enables data processing	Same
Mouse and Keyboard	Standard mouse and keyboarded	Add touchpad mouse
Console	Drives the magnetic signals from Emitter Pad to Workstation	Same
Emitter Pad	Generates magnetic field	Same
Patient tracker	Compensates on patient movement (reusable or disposable)	Same
Registration Probe	Enables correlation between patient's face and CT image	Same
Isolation Transformer	Adjusting power input to the system	Same

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Summary of Technological Characteristics

The subject device has the same technological characteristics as the predicate device, with addition of:

- Patient Data Archive
  Note: The Patient Data Archive is a new Software Function, although, being a Medical Device Data System (MDDS), it is not regulated by the FDA.
- Instrument Hub improvement
- Support of additional navigated tools
- Software enhancements
  - Segmentation manual editing
  - Path to Target 3D visualization
- Cables robustness improvement
- Optional touchpad mouse

Non-clinical Performance Data:

The TruDi® Navigation System V3 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 non-clinical tests were performed:

1. Location Accuracy tests, where the TruDi® Navigation System electromagnetic locations were compared to the locations provided by a highly accurate robot system over its entire navigation volume

2. Software functional tests, covering the complete system functionality, and including error handling, usability and time performance (latency).

3. Safety, and EMC tests were performed by a nationally recognized testing laboratory to verify compliance with safety and EMC standards for medical devices.

4. 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.

The proposed TruDi® Navigation System V3 passed all tests in accordance with specified 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 V3 performs as intended.

Conclusion:

The modified TruDi® Navigation System V3 is substantially equivalent to the currently cleared TruDi® Navigation System V2 based on the completion of non-clinical bench testing as well as similar principles of design, operation and indications for use.