



Food and Drug Administration  
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October 24, 2016

Biosense Webster  
Ms. Melissa C. Schultz  
Manager, Regulatory Affairs  
3333 Diamond Canyon Road  
Diamond Bar, CA 91765

Re: K161701  
Trade/Device Name: CARTO ENT System  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: PGW  
Dated: September 21, 2016  
Received: September 22, 2016

Dear Ms. Schultz:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Eric A. Mann -S**

for Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K161701

Device Name  
CARTO® ENT System

Indications for Use (Describe)

The CARTO® ENT System is intended for use during intranasal and paranasal image-guided navigation procedures for patients who are eligible for sinus procedures.

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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### [807.92(a)(1)] Submitter Information

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**Date Summary Prepared:** September 16, 2016

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

**Device Trade** CARTO<sup>®</sup> ENT Navigation System  
**Common Name:** Image Guided Surgery System  
**Device** Class II  
**Regulation** 21 CFR 882.4560  
**Classification** Ear, Nose, and Throat Manual Surgical Instrument (21 CFR 882.4560)  
**Product Code:** PGW

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

**Predicate Devices:** Fiagon Navigation System (K133573)  
**Reference Devices:** CARTO<sup>®</sup> 3 EP Navigation System (K133916)

### [807.92(a)(4)] Device Description

**Device Description:** The CARTO<sup>®</sup> ENT System is intended to be used during intranasal and paranasal surgical procedures to help ENT physicians to track and display the real-time location of the tip of navigated instruments relative to pre-acquired reference images, such as CT. The CARTO<sup>®</sup> ENT device enables ENT physicians to access sphenoid, frontal, and maxillary sinuses by using the system magnetic tracking technology. The system incorporates a Navigation Console, Field Ring, Instrument Hub, Patient Tracker, Workstation and accessories. A magnetic field generated by the 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 CARTO<sup>®</sup> ENT System is intended as an aid for precisely locating anatomical structures during intranasal and paranasal image-guided navigation procedures.

**Difference in Indications from Predicate Device:** The difference in indications for use between the subject and predicate devices is supported is presented in Table 1 of this summary.

#### [807.92(a)(6)] Technical Characteristics

**Technological Characteristics:** The substantial equivalence of the CARTO<sup>®</sup> ENT Navigation System to the predicates is shown by similarity in intended use, indications for use, and performance.

Like the predicate Fiagon System, the CARTO<sup>®</sup> ENT Navigation System is an image-guided navigation system intended for use during paranasal surgical procedures. ENT physicians can track and display the real-time location of the tip of navigated instruments relative to pre-acquired CT images.

Like the predicate, the CARTO<sup>®</sup> ENT 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 image sets as reference images for the image-based model.

**Table 1: Comparison of Predicate and Subject Device**

Attribute	Fiagon Navigation System	CARTO <sup>®</sup> ENT Navigation System
	Predicate	Subject Device
Intended Use	Intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.	Intended for use during intranasal and paranasal image-guided navigation procedures
Fundamental Scientific Technology	Electromagnetic tracking	Same
Control Mechanism	Software controlled	Same
Navigation method	Electromagnetic location in reference to registered CT/MR background of patient head	Same, CT only
Registration method	Fiducial matching and surface matching	Same
Bench test location accuracy	0.9 mm (Standard deviation 0.34 mm)	0.55 mm (Standard deviation 0.7 mm)
Simulated Use Accuracy	1.79 mm (Standard deviation 0.4 mm)	0.63 mm (Standard deviation 0.2 mm)
Location update rate	15 to 45 Hz	10 Hz
Main components	1. Navigation unit 2. Head rest with field generator 3. Patient reference localizer 4. Navigation instrument	1. Same (Navigation console) 2. Same (Field Ring) 3. Same (Patient Tracker) 4. Same (Acclarent NavWire, not included with CARTO <sup>®</sup> ENT System)
Supported navigation instruments	Flexible tip instruments with magnetic sensor on instrument tip	Same
Registration tools	Registration pointer, manual acquisition of anatomic points and surfaces	Registration probe, manual or force sensing acquisition of anatomic points and surfaces
Registration Probe Sensing	No	Force measurement range 1 to 10 gr. Automatic acquisition of registration points or surfaces.

The primary difference between the Fiagon Navigation System and CARTO<sup>®</sup> ENT Navigation System is that on top of manual registration supported by the Fiagon system, where the physician manually selects points and surfaces on the patient face to be registered, the CARTO<sup>®</sup> ENT System also supports a force sensing registration mode, where points and surfaces are automatic acquired when adequate pressure is applied with the registration probe on the patient face. Since the physician is instructed to verify the quality of the registration, this addition does not raise new issues of safety and effectiveness.

### [807.92(b) (1)] Determination of Substantial Equivalence

#### **Non-Clinical Performance Data:**

The CARTO<sup>®</sup> ENT System 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 CARTO<sup>®</sup> ENT System electromagnetic locations were compared to the locations provided by a, very 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 and EMC 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 CARTO<sup>®</sup> ENT System in a simulated clinical environment, to assess the execution of a complete sinuplasty procedure workflow and to qualitatively estimate the system clinical accuracy.

The results of the above tests support the safety of the device and demonstrate that the CARTO<sup>®</sup> ENT System perform as intended in the specified use conditions. The tests also demonstrate that the device performs comparably to the predicate device for the same intended use.

### [807.92(b) (2)] Determination of Substantial Equivalence

#### **Clinical Performance Data:**

Clinical data was not necessary for the CARTO<sup>®</sup> ENT System. The performance data demonstrated that the device performs as intended.

### [807.92(b) (3)] Conclusion

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**Conclusion from Non-Clinical and Clinical Tests**

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the CARTO<sup>®</sup> ENT Navigation System has been shown to be substantially equivalent to the predicate device identified in this submission, and does not present new issues of safety or effectiveness.