March 10, 2018

Acclarent, Inc.
James Patrick Garvey II
Associate Director, Regulatory Affairs
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K173628
Trade/Device Name: Acclarent® ENT Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: February 8, 2018
Received: February 9, 2018

Dear James Patrick Garvey II:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -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

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)*

K173628

Device Name

ACCLARENT® ENT Navigation System

Indications for Use *(Describe)*

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.

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

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Date Summary Prepared: January 19, 2018

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

Device Trade Name: ACCLARENT® ENT 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 Device: CARTO® ENT Navigation System
510(k)#: K161701

[807.92(a)(4)] Device Description

Device Description: The ACCLARENT® ENT Navigation 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 ACCLARENT® ENT Navigation System enables ENT physicians to access sphenoid, frontal, and maxillary sinuses by using the system magnetic tracking technology, identical to the predicate device.

The system incorporates a Navigation Console, Field Ring, Instrument Hub, Patient Tracker, Registration Probe, Field Ring and Holder, 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 ACCLARENT® ENT Navigation System is intended for use during intranasal and paranasal image-guided navigation procedures for patients who are eligible for sinus procedures.
Difference in Indications from Predicate Device:	The intended use of the device is unchanged from the predicate.
[807.92(a)(6)] Technical Characteristics	
Technological Characteristics:	The substantial equivalence of the ACCLARENT® ENT Navigation System to the predicates is shown by similarity in intended use, indications for use, and performance. Like the predicate CARTO® ENT System, the ACCLARENT® 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 ACCLARENT® ENT Navigation 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. The instructions for use and product labels have been updated to reflect the revised device.
Non-clinical Performance Data:	The ACCLARENT® ENT Navigation 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 ACCLARENT® ENT Navigation 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, 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 ACCLARENT® ENT Navigation 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 proposed ACCLARENT® ENT Navigation System 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 ACCLARENT® ENT Navigation System was substantially equivalent to the predicate device. The performance data demonstrated that the device performs as intended.

Conclusion:

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