DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 23, 2016

APN Health, LLC
% Grace Bartoo
Decus Biomedical Inc.
2342 Shattuck Ave, #333
Berkeley, California 94704

Re: K152160
Trade/Device Name: Navik 3D
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: January 27, 2016
Received: January 28, 2016

Dear Grace Bartoo:

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.

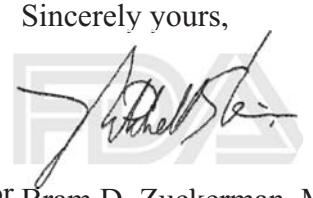
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152160

Device Name
Navik 3D

Indications for Use *(Describe)*
Navik 3D is intended for catheter-based atrial and ventricular mapping using compatible catheters, and acquired data from compatible fluoroscopy systems and patient recording and monitoring systems. Navik 3D is intended to provide 3D location of these catheters from acquired 2D fluoroscopic images. The device allows real-time display of cardiac maps in a number of different formats, including anatomical maps, cardiac electrical activation maps and cardiac voltage maps.

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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5.0 510(K) SUMMARY

Submitter	APN Health, LLC
Contact Person	Grace Bartoo, PhD, RAC, CBA, FRAPS
Title	Regulatory Consultant
Phone	650-488-7799
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Email	grace@decusbiomedical.com
Date Summary Was Prepared	January 26, 2016
Trade or Proprietary Name	Navik 3D™
Model Number	Navik 3D 1.0
Common or Usual Name	Cardiac mapping system
Regulation Number	21 CFR 870.1425
Product Code	DQK, Programmable Diagnostic Computer
Device Class	Class II
Predicate Device	Trade Device Name: CARTO® 3 System V3.0 Manufacturer: Biosense Webster, Inc. Address: 333 Diamond Canyon Road, Diamond Bar, CA 91765 Regulation Number: 21 CFR 870.1425 Regulation Name: Programmable Diagnostic Computer Regulatory Class: Class II Product Code: DQK 510(k) Number: K120550 510(k) Clearance Date: May 7, 2012

5.1 Description of the Device

Navik 3D™ is a multi-component computer system that utilizes image processing methods to provide three-dimensional (3D) location of catheters in real-time from acquired two-dimensional (2D) fluoroscopic (fluoro) images. In addition, body surface electrocardiogram (ECG) and intracardiac electrogram (EGM) signals obtained from the patient recording and monitoring systems that already exist in the electrophysiology (EP) lab are digitized and displayed.

Navik 3D utilizes data points from 3D catheter location and ECG-intracardiac EGM signals and uses this information to create and display 3D maps of the human heart. It does not require special catheters or patches, specially trained technicians, or fluoroscopy exposure beyond standard of care.

5.2 Indications for Use

Navik 3D is intended for catheter-based atrial and ventricular mapping using compatible catheters, and acquired data from compatible fluoroscopy systems and patient recording and monitoring systems. Navik 3D is intended to provide 3D location of these catheters from acquired 2D fluoroscopic images. The device allows real-time display of cardiac maps in a number of different formats, including anatomical maps, cardiac electrical activation maps and cardiac voltage maps

5.3 Summary of Technological Characteristics Comparison

Table 5-1 shows the similarities and differences of the technology between the two products. The key difference is that the predicate device uses a magnetic location pad, multiple patches around the

patient's chest, a proprietary catheter with a built in magnetic sensor and a patient interface unit (PIU) to acquire 3D catheter location information, whereas Navik 3D uses an image processing approach to analyze 2D fluoroscopic images to identify the 3D catheter location and can use any compatible catheters. While these methods are different, the physical principles behind each technology are well-established and do not raise new questions of safety or effectiveness.

Table 5-1 Summary of Technological Characteristics Comparison

Technological Characteristics		
Characteristic	**Predicate Device**	**Subject Device**
System Type	Electromagnetic and catheter-based atrial and ventricular mapping system	Image and signal processing based atrial and ventricular mapping system
Primary Feature	Displays anatomical and electrical maps such as activation and voltage maps of the human heart in real-time using magnetic navigation techniques and ECG-EGM analysis	Displays anatomical and electrical maps such as activation and voltage maps of the human heart in real-time using fluoroscopic image processing techniques and ECG-EGM analysis
3D Location Technology	Electro anatomic location and ECG-EGM signal processing	Fluoroscopic image and ECG-EGM signal processing
Compatible Catheters	Proprietary catheter with in-built magnetic sensor	Any compatible mapping and ablation catheter.
Display(s)	Color monitor	Color monitor and Apple iPad®
Control	Standard keyboard/mouse	iPad controller and/or standard keyboard/mouse
Inputs Required	Proprietary and non-proprietary catheters and patches, ECG and EGM data from the patient	Fluoroscopic images, ECG and EGM data from the patient recording and monitoring system, ECG patches (for motion tracking only)
Map Types Generated in Real-Time	3D cardiac maps including: anatomical maps, cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential (voltage) maps, cardiac chamber geometry maps and Complex Fractionated Atrial Electrogram (CFAE) maps	3D cardiac maps including: anatomical maps, cardiac electrical activation maps and cardiac voltage maps
Fluoroscopic Image Displayed	Not real-time	Real-time with 3D map projected on fluoro image if desired
Signal Information Displayed	Acquired patient signals, including body surface ECG and intracardiac EGMs	Imported signals, including body surface ECG and intracardiac EGMs, from the patient recording and monitoring system
3D Viewing of Maps	Standard 3D rendering, coloring and user rotation and viewing methods	Standard 3D rendering, coloring and user rotation and viewing methods
Hardware Design and Materials	Off-the-shelf information technology (IT) hardware: computer and monitor Proprietary catheters, patient interface unit and accessories	Off-the-shelf IT hardware: computer, router, graphics card and iPad Data Acquisition Module, based on commercially available frame grabber

Technological Characteristics		
Characteristic	**Predicate Device**	**Subject Device**
		and analog to digital (A/D) conversion board
CT/MRI/ Ultrasound Registration	Includes optional modules for integration of computed tomography (CT), magnetic resonance imaging (MRI) and ultrasound	None
Track Multiple Catheters	Visualization and tracking of multiple catheters. No fluoroscopic images are shown with the catheter tracking.	All catheters visualized on fluoro screen with real-time fluoro data input. Tracking of the mapping catheter only.
Motion compensation	Compensated (table) and uncompensated (patient) motion	Using ECG patch detection algorithms, compensates for patient and table motion
Non-Clinical Performance Testing	Underwent bench and animal testing to verify the modified features and to demonstrate with regression testing that the new features did not negatively affect existing features	Detailed performance testing conducted to demonstrate performance characteristics. Animal and bench (phantom) study protocols executed to enable performance comparison with predicate device. The device has been demonstrated to be in compliance with IEC 62366-1 Edition 1.0 2015-02 and IEC 62304 First Edition 2006-05.

5.4 Performance Data

APN Health conducted the following non-clinical performance tests:

- Design verification and validation testing.
- A phantom study to directly compare tip location accuracy performance by making measurement simultaneously on the predicate device CARTO and Navik 3D systems.
- An electrogram analysis and ECG gating study to directly compare cycle length (CL), local activation time (LAT) and EGM voltage measurements against reference signals.
- Extensive animal testing where navigation and mapping capabilities between Navik 3D and the predicate device were directly compared.

Based upon the results of these studies, it was determined the Navik 3D performance was substantially equivalent to the predicate device.

5.5 Substantial Equivalence Conclusion

The predicate device and Navik 3D have the same intended use, to provide 3D cardiac mapping. While CARTO has more indications for use than Navik 3D, the Navik 3D system's indications for use are a subset of those of CARTO.

From a technological perspective, CARTO uses a magnetic localization method to obtain the 3D location of the catheter tip whereas Navik 3D utilizes image processing methods. Because of these differences in approach, CARTO includes more hardware elements, such as a magnetic location pad, patches around the chest of the patient, a PIU and other hardware. Additionally, CARTO requires use of a specific mapping catheter with magnetic sensors, whereas Navik 3D uses any compatible mapping and ablation catheters. CARTO also provides additional functionality, such as generating EGM signals, whereas Navik 3D takes output from the patient recording and monitoring system and the fluoroscopy system as inputs and performs digitization. While there are differences in the technology, the data acquisition technology is well-characterized. Additionally, the image processing approach of Navik 3D is founded on strong physics principles, and both the non-clinical and animal study performance data have shown substantially equivalent performance during simultaneous comparison studies Therefore, the differences in the technology characteristics does not raise new questions of safety or effectiveness and one can conclude that Navik 3D is substantially equivalent to the predicate device, CARTO.