June 24, 2019

Centerline Biomedical, Inc.
℅ Lauren Smith
Senior Quality and Regulatory Engineer
JALEX Medical
30311 Clemens Rd Suite 5D
Westlake, Ohio 44145

Re: K190106
Trade/Device Name: Intra-Operative Positioning System; Simple Curve Catheter, Reverse Curve Catheter ; Angled Tip Guidewire ; Tracking Pad ; Guidewire Handle
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 21, 2019
Received: June 24, 2019

Dear Lauren Smith:

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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190106

Device Name
Intra-Operative Positioning System (IOPS)

Indications for Use *(Describe)*
The IOPS (Intra-Operative Positioning System) is intended for the evaluation of vascular anatomy as captured via 3D modeling from previously acquired scan data. It is intended for real time tip positioning and navigation using sensor equipped compatible catheters and guidewires used in endovascular interventions in the descending aorta. The system is indicated for use as an adjunct to fluoroscopy. The IOPS does not make a diagnosis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

VIII. 510(k) Summary

Submitted By: Centerline Biomedical, Inc.
10000 Cedar Ave
Cleveland, Ohio 44106

Date: 6/7/2019

Contact Person: Lauren Smith, Senior Quality/Regulatory Engineer
Contact Telephone: 440.541.0060
Contact Fax: 440.933.7839

Device Trade Name: Intra-Operative Positioning System (IOPS)
Device Classification Name: Programmable diagnostic computer (21 CFR 870.1425)
Device Classification: Class II
Reviewing Panel: Cardiovascular
Product Code: DQK
Primary Predicate Device: St. Jude Medical, MediGuide Technology (K162643)
Secondary Predicate Devices: MediGuide Enabled Livewire Steerable Electrophysiology Catheter (K151622)
CPS Excel MediGuide Enabled Guidewire (K120298)

Device Description:
The IOPS system displays the position and orientation of sensor equipped guidewires and catheters utilizing electromagnetic tracking technology. The system enables mapping of the patient's vascular system utilizing previously acquired CT scan data. IOPS registers the location and orientation of the sensors in real time superimposing navigation of the catheters and guidewires to the patient's vascular map.

The patient's vascular map is generated using a contrast enhanced, high resolution CT scan. The IOPS creates a 3D rendering of that structure. A bone segmented 3D rendering may optionally be created to provide anatomical, skeletal points visible in relation to the vascular rendering.

The main principles of action for the IOPS are similar to those used in Global Positioning System (GPS) tracking. The navigation components generate a time-varying magnetic field in which the position and orientation of sensor embedded catheters and guidewires are read. The computing unit visually displays the location of the sensor on the patient's vascular map.

The system is intended for use by trained clinicians for patients undergoing endovascular interventional procedures of the descending aorta, such as stent grafting. The system promotes more efficient use of operating room time and minimizes the need for fluoroscopy. The clinician uses the IOPS catheters and guidewires to navigate through the aorta to access branch vessels

near to, or involved in, the lesion. The catheters and guidewires are not for angiographic or diagnostic use.

IOPS is composed of a mobile cart which houses a monitor, computer, keyboard, pointing device, uninterruptable power supply (UPS), and cables. IOPS includes a tracking system composed of a system control unit (SCU), system interface unit (SIU), field generator, mounting brackets, and cables. These components are reusable and not patient contacting. The IOPS is integrated with software to generate the mapping and overlay of the live sensors. The IOPS works with a sensor embedded catheter, guidewire, and tracking pad which are provided sterile and not intended for re-use.

Intended Use:
The IOPS (Intra-Operative Positioning System) is intended for the evaluation of vascular anatomy as captured via 3D modeling from previously acquired scan data. It is intended for real time tip positioning and navigation using sensor equipped compatible catheters and guidewires used in endovascular interventions in the descending aorta. The system is indicated for use as an adjunct to fluoroscopy. The IOPS does not make a diagnosis.

Substantial Equivalence:

	Subject Device Centerline Biomedical IOPS	**Predicate Device MediGuide Technology System**	**Comparison**
Product Code	DQK	DQK	Same
Intended Use/Indications for Use	The IOPS (Intra-Operative Positioning System) is intended for the evaluation of vascular anatomy as captured via 3D modeling from previously acquired scan data. It is intended for real time tip positioning and navigation using sensor equipped compatible catheters and guidewires used in endovascular interventions in the descending aorta. The system is indicated for use as an adjunct to	The MediGuide™ Technology System is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide Enabled™/Sensor Enabled™ (equipped with a magnetic sensor) invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background.	The IOPS is only intended for the evaluation of vascular anatomy for vascular interventions only. Both sensors enable real time tip positioning and navigation of magnetic sensor equipped devices.

	fluoroscopy. The IOPS does not make a diagnosis.		
Device Description	The IOPS system displays the position and orientation of sensor equipped guidewires and catheters utilizing electromagnetic tracking technology. The system enables mapping of the patient's vascular system utilizing previously acquired CT scan data. IOPS registers the location and orientation of the sensors in real time superimposing navigation of the catheters and guidewires to the patient's vascular map.	MediGuide Technology enables navigation of devices on pre-recorded X-ray images allowing the physician to reduce the duration of live X-ray during a procedure. MediGuide Technology applies 3D visualization and precise navigation to pre-recorded 2D X-ray images and can be used by the physician to perform complex electrophysiology procedures and CRT implants. MediGuide Technology is analogous to a global positioning system (GPS) in that it uses a low powered electromagnetic field to locate device-based sensors in three-dimensional space. The system uses this location information to overlay MediGuide™ Enabled/Sensor Enabled™ devices on the corresponding pre-recorded X-ray image, which allows the physician to reduce the duration of live X-ray during a procedure. MediGuide creates a real-time clinical environment by compensating for patient motion, respiration and heart rate variability.	IOPS enables navigation of devices on a 3D rendering of the vasculature. Both systems compensate for patient motion.
Class	Class II	Class II	Same

Classification Identification	21 CFR 870.1425 Programmable Diagnostic computer	21 CFR 870.1425 Programmable Diagnostic computer	Same
System dedicated tracking devices	2 Catheters 1 Guidewire	Variety of catheters, guidewire, connector accessories	Both systems include magnetic sensor equipped catheters and guidewires

Non-Clinical Testing:

Performance testing was conducted to demonstrate the performance and accuracy of the IOPS and to verify that it does not raise any new safety and effectiveness concerns. Test results indicate that the IOPS is substantially equivalent to the predicate device and does not raise any new safety or effectiveness concerns. All testing was performed on production equivalent devices.

- IEC 60601-1 and IEC 60601-1-2 Electrical Safety and Electromagnetic Compatibility Testing
- Biocompatibility testing for guidewires and catheters (Externally Communicating Device, Circulating blood contact, A – limited ≤ 24h) per ISO 10993
- Biocompatibility testing for tracking pads (Surface device, intact skin, A – limited ≤ 24h)
- Sterilization validation per ISO 11135
- Packaging integrity testing for sterile components:
    - Accelerated aging per ASTM F1980
    - Bubble leak test per ASTM F2096
    - Seal strength per ASTM F88
    - Distribution testing per ASTM D4169
- Software documentation and validation per:
    - General Principles of Software Validation; Final Guidance for Industry and FDA Staff
    - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for Industry and FDA Staff
- Mechanical evaluation of catheters per ISO 10555-1 and guidewires per FDA's Guidance on Coronary and Cerebrovascular Guidewires
- Summative Usability testing in a simulated use environment per Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff
- Porcine animal studies for usability testing and functional evaluation
- Functional performance testing
    - Lag testing
    - Accuracy testing per ASTM F2554
    - X-ray artifact testing