March 6, 2025

Centerline Biomedical, Inc.
Kevin Reed
Director, Quality & Regulatory
4535 Renaissance Pkwy
Cleveland, Ohio 44128

Re: K243842
Trade/Device Name: Intra-Operative Positioning System (IOPS®)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQY, DQX
Dated: December 13, 2024
Received: December 13, 2024

Dear Kevin Reed:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MARCO CANNELLA -S

for

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243842

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 peripheral, aortic and aortic side branch vasculature. 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."

SUBMITTER

Centerline Biomedical, Inc.
4535 Renaissance Pkwy
Cleveland, OH 44128

Phone: 330-577-5033
Email: kevin.reed@centerlinebiomedical.com

Contact Person: Kevin Reed
Date Prepared: 21 FEB 2023

DEVICE

Trade Name:	Intro-Operative Positioning System (IOPS®)
Common Name:	Programmable diagnostic computer
Classification Name:	Computer, diagnostic, programmable
Regulatory Class:	II
Product Codes:	DQK, DQY, DQX
Regulation Number:	870.1425

PREDICATE DEVICE

The legally marketed device to which equivalence is being claimed [807.92(a)(3)] is as follows:

510(k) Number	Name	Product Code
K190106	Intra-Operative Positioning System (IOPS)	DQK
K230309	Intra-Operative Positioning System (IOPS®)	DQK
K241243	Intra-Operative Positioning System (IOPS®) Viewpoint	DQK
K242133	Intra-Operative Positioning System (IOPS®)	DQK

Primary predicate is listed first. The predicates have not been the subject of any design-related recalls.

DEVICE DESCRIPTION

The Intra-Operative Positioning System (IOPS) consists of a surgical navigation technology and a number of associated accessories. The navigation technology is a non-contact reusable multi-patient use device. The associated accessories are single use devices provided sterile (EtO).

The IOPS displays the position and orientation of sensor equipped catheters, guidewires, and tracking pad 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 displayed on a monitor. The system is for use as an adjunct to fluoroscopy and does not make a diagnosis.

The associated accessories include:
- Guidewire
- Catheters
- Fiducial Tracking Pad
- Guidewire Handle

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 peripheral, aortic and aortic side branch vasculature. The system is indicated for use as an adjunct to fluoroscopy. The IOPS does not make a diagnosis.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Indications for Use statement for the IOPS and its associated accessories is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the evaluation of vascular anatomy as captured via 3D modeling from previously acquired scan data and for real time tip positioning and navigation using sensor equipped compatible catheters and guidewires.

All technological characteristics of the IOPS and its associated accessories are the same as the predicate devices except for IOPS software version.

Table 1 lists the differences between the subject device and the predicate device.

Table 1: Summary Comparison

	Subject Device	**Predicate Device (K190106, K230309, K2414243, K242133)***	**Discussion**
Trade Name	Intra-Operative Positioning System (IOPS)	Intra-Operative Positioning System (IOPS)	Same
Model Name/Number	Mobile Cart MC-1	Mobile Cart MC-1	Same
Product Code	DQK	DQK	Same
Class	II	II	Same
Classification Identification	870.1425	870.1425	Same
Device Description	The IOPS 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 IOPS 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.	Same
Device Accessories	• IOPS Guidewire (ATW-2) • IOPS Viewpoint Simple Curve Catheters	• IOPS Guidewire (ATW-2) • IOPS Viewpoint Simple Curve Catheters	Similar The expanded use of the

	(C00751; C01251) • IOPS Viewpoint Double Curve Catheters (C00752; C01252) • IOPS Fiducial Tracking Pad (T02111) • IOPS Guidewire Handle (H01035)	(C00751; C01251) • IOPS Viewpoint Double Curve Catheters (C00752; C01252) • IOPS Fiducial Tracking Pad (T02111;TP-1) • IOPS Guidewire Handle (H01035)	subject device in this submission is not intended to be used with the first generation IOPS Tracking Pad (TP-1).
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 peripheral, aortic and aortic side branch vasculature. The system is indicated for use as an adjunct to fluoroscopy. The IOPS does not make a diagnosis.	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.	The Indications for Use statement for the IOPS and its associated accessories is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the evaluation of vascular anatomy as captured via 3D modeling from previously acquired scan data and for real time tip positioning and navigation using sensor equipped compatible catheters and guidewires. The subject device has been evaluated through design validation.
Intended Use Population	Adults Only	Adults Only	Same
Software Version	1.5.81	1.0.5056	The difference in the software version does not raise new questions of safety or effectiveness. The subject device has been evaluated through software verification testing.

* The predicate device was originally cleared in K190106 and cleared with updated labeling (changed Applied Part designations from Type BF to Defibrillation-Proof Type BF) in K230309. IOPS Viewpoint Catheters were cleared in K241243. IOPS Fiducial Tracking Pad and Guidewire Handle were cleared in K242133.

PERFORMANCE DATA

Bench Testing

Software verification was conducted to establish equivalency to the predicate device in safety and effectiveness. There are no hardware changes to IOPS and its associated accessories and therefore Electrical, Mechanical and Thermal Safety Testing is not needed.

Design Validation, including usability testing, was performed to support the inclusion of all peripheral,

aortic and aortic side branch vasculature vessels in the indications for use statement and to establish equivalency to the predicate device in safety and effectiveness. These studies included physician targeting of three regions for cannulation: branches of the aortic arch, distal branches of the descending aorta, and branches of the peripheral vasculature. In addition, technicians were given test case scenarios and asked to place the tracking pad in each of the three proposed expanded indications regions.

Animal Testing

No animal testing was completed as a part of this submission.

Clinical Testing

No clinical testing was completed as a part of this submission.

CONCLUSIONS

The change in the indications for use does not raise new or different questions of safety or effectiveness. The successful completion of non-clinical testing demonstrates that IOPS performs as intended and is substantially equivalent to the predicate device.