June 10, 2026

Centerline Biomedical
Carroll Martin
Sr. Regulatory Affairs Manager
4535 Renaissance Pkwy.
Warrensville Heights, Ohio 44128

Re: K261329
Trade/Device Name: IOPS® (Intra-Operative Positioning System)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK, DQY, DQX
Dated: April 22, 2026
Received: April 22, 2026

Dear Carroll Martin:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for: MARCO CANNELLA -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261329

Please provide the device trade name(s).

IOPS® (Intra-Operative Positioning System)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary for the IOPS® (Intra-Operative Positioning System)

I. Device Name

Trade Name	IOPS® (Intra-Operative Positioning System)
Device Class	Class II
Common/Usual Name	Programmable Diagnostic Computer
Classification Name	Computer, diagnostic, programmable
Product Codes	DQK, DQY, DQX
Regulation Number	870.1425

II. Submitter Information

Applicant Name	Centerline Biomedical, Inc.
Applicant Address	4535 Renaissance Parkway, Warrenville Heights, Ohio 44120
Telephone Number	216-200-6366
Date of Preparation	22APR2026
Contact Person	Carroll L. Martin, Sr. Regulatory Affairs Manager

III. Predicate Device

The predicate device to which substantial equivalence is claimed is the Intra-Operative Positioning System (IOPS®), cleared under K243842.

IV. Device Description

The IOPS® (Intra-Operative Positioning System) displays the position and orientation of sensor-equipped IOPS® guidewires and IOPS® catheters utilizing electromagnetic tracking technology. The system enables mapping of the patient's vascular system utilizing previously-acquired scan data (CT). The Intra-Operative Positioning System (IOPS) tracks the location and orientation of the sensors in real time, superimposing navigation of the IOPS Catheter and IOPS Guidewire to the patient's vascular map.
The system 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 Intra-Operative Positioning System (IOPS) is indicated 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 Intra-Operative Positioning System (IOPS) does not make a diagnosis.
The associated accessories include:
- Guidewire
- Catheters

- Fiducial Tracking Pad
- Guidewire Handle

The system consists of three major sections: the cart, the tracking system (Sensor Interface Unit (SIU), System Control Unit (SCU) and Field Generator) and the accessories.

V. Indications for Use

The IOPS (Intra-Operative Position 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.

VI. Substantial Equivalence

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Modified Intra-Operative Positioning System	Equivalence Discussion
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 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 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.	Identical
Onboard Monitor	Displays patient maps and superimposed images	Displays patient maps and superimposed images	Identical
Computer	Provides an operating system	Provides an operating system	Identical
Keyboard	Allows data input	Allows data input	Identical
Mouse	Allows data input	Allows data input	Identical

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Modified Intra-Operative Positioning System	Equivalence Discussion
Uninterruptible power supply (UPS)	Provides power when electricity is not available	Provides power when electricity is not available	Identical
Power Requirements	120V, 60HZ	120V, 60HZ	Identical
Voltage Transformer	Not present	Not present	Identical
Video Splitter	The video out enables the Mobile Cart to simultaneously display the user interface on the onboard monitor and provide a video signal for an external display.	The video out enables the Mobile Cart to simultaneously display the user interface on the onboard monitor and provide a video signal for an external display.	Identical
Cables	Allows data transfer	Allows data transfer	Identical
IOPS Software Application	Software which creates vascular map used to show location of sensorized catheter and guidewires in real time. Vascular map is generated from a preoperative CT scan which is processed to segment the vasculature and perform centerline and surface analysis. Version 1.5	Software which creates vascular map used to show location of sensorized catheter and guidewires in real time. Vascular map is generated from a preoperative CT scan which is processed to segment the vasculature and perform centerline and surface analysis. Version 1.6	Different The new software version addresses anomalies discovered through the use of device and also provides new features to the user. These changes do not affect the safety and effectiveness of the device. They only address inconvenience to the user and provide for desired functionality

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Modified Intra-Operative Positioning System	Equivalence Discussion
System Control Unit (SCU)	Collects information from the SIUs, calculates the position and orientation of each sensor and interfaces with the host computer.	Collects information from the SIUs, calculates the position and orientation of each sensor and interfaces with the host computer.	Identical
Sensor Interface Unit (SIU)	Amplifies and digitizes the electrical signals from the sensors and provides an increased distance between the SCU and sensors, while minimizing the potential for data noise	Amplifies and digitizes the electrical signals from the sensors and provides an increased distance between the SCU and sensors, while minimizing the potential for data noise	Identical
Electromagnetic Field Generator	Emits a low-intensity, varying electromagnetic field and establishes the position of the tracking volume	Emits a low-intensity, varying electromagnetic field and establishes the position of the tracking volume	Identical
Mounting brackets	Affixes field generator to operating table	Affixes field generator to operating table	Identical
USB Ports	Present. Allows the user to copy fluoroscan images from a flash drive that was obtained from the user's fluoroscan. These images are used with IOPS to create vessel and bones models for use during procedures.	Present. Allows the user to copy fluoroscan images from a flash drive that was obtained from the user's fluoroscan. These images are used with IOPS to create vessel and bones models for use during procedures.	Identical

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Modified Intra-Operative Positioning System	Equivalence Discussion
Functionality	The IOPS (MC-1) 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 IOPS (MC-1) 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.	Identical

Device Accessories	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Modified Intra-Operative Positioning System	Equivalence Discussion
IOPS Viewpoint Simple Curve Catheters (C00751; C01251) and Double Curve Catheters (C00752; C01252)	6 Fr catheters equipped with multiple tracking sensors allowing the IOPS to detect and visualize the catheter tip position and shape, in real time, on a 3D rendering of the patient's vascular map. They are available in two tip shape configurations: simple curve and double curve. Each curve is offered in two different working lengths (75cm and 125cm).	6 Fr catheters equipped with multiple tracking sensors allowing the IOPS to detect and visualize the catheter tip position and shape, in real time, on a 3D rendering of the patient's vascular map. They are available in two tip shape configurations: simple curve and double curve. Each curve is offered in two different working lengths (75cm and 125cm).	Identical
	Shelf Life: 1 year	Shelf life: 2 years	Different Testing showed that extension of shelf life has no effect on safety or effectiveness.
	Sterilization: EO in a rigid chamber.	Sterilization: EO in a flexible bag system. Data provided in section 002_Device Description and Principles of Operation in this submission.	Different The change has no impact on the safety or performance of the device. Requirements for EO and ECH residuals, and device functionality were met.

Device Accessories	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Modified Intra-Operative Positioning System	Equivalence Discussion
IOPS Guidewire (ATW-2)	Guidewire is a 0.035" diameter wire with a single sensor at the distal end used to navigate through vasculature to facilitate placement of a catheter.	Guidewire is a 0.035" diameter wire with a single sensor at the distal end used to navigate through vasculature to facilitate placement of a catheter.	Identical
	Shelf life: 2 years	Shelf life: 2 years	Identical
	Sterilization: EO in a rigid chamber.	Sterilization: EO in a rigid chamber.	Identical
IOPS Fiducial Tracking Pad (T02111)	Fiducial Tracking Pad is equipped with a single tracking sensor allowing IOPS to track gross patient motion to allow maintenance of patient registration during endovascular procedure. It will not track minor patient motion such as breathing or cardiac movement. The tracking pad is equipped with radiopaque beads which allow registration of a conebeam CT scan of the patient in their current position to a previously acquired CT scan.	Fiducial Tracking Pad is equipped with a single tracking sensor allowing IOPS to track gross patient motion to allow maintenance of patient registration during endovascular procedure. It will not track minor patient motion such as breathing or cardiac movement. The tracking pad is equipped with radiopaque beads which allow registration of a conebeam CT scan of the patient in their current position to a previously acquired CT scan.	Identical
	Shelf life: 3 years	Shelf life: 3 years	Identical
	Sterilization: EO in a flexible bag: (K242133)	Sterilization: EO in a flexible bag: (K242133)	Identical

Device Accessories	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Modified Intra-Operative Positioning System	Equivalence Discussion
IOPS Guidewire Handle (H01035)	Guidewire Handle is a non-sensorized handle that connects to an IOPS sensorized guidewire to allow detection and visualization of the guidewire tip position, in real time, on a 3D rendering of the patient's vascular map. It consists of a handle housing which encases a cable assembly that connects to a sensorized IOPS Guidewire.	Guidewire Handle is a non-sensorized handle that connects to an IOPS sensorized guidewire to allow detection and visualization of the guidewire tip position, in real time, on a 3D rendering of the patient's vascular map. It consists of a handle housing which encases a cable assembly that connects to a sensorized IOPS Guidewire.	Identical
	Shelf-Life: 3 years (K242133)	Shelf-Life: 3 years (K242133)	Identical
	Sterilization: EO in a flexible bag (K242133)	Sterilization: EO in a flexible bag (K242133)	Identical

VII. Performance Testing

System and software verification testing was conducted to establish equivalency to the predicate device in safety and effectiveness and to ensure the Intra-operative Positioning System met established requirements.

Also, packaging and catheter visual inspection, package integrity (bubble leak, seal strength) catheter dimensional measurement, sensor functionality, sensor placement, tensile strength, and simulated use testing were conducted to verify the extension of catheter shelf life.

VIII. Animal and Clinical Testing

No animal or clinical testing was conducted.

IX. Conclusions

The modifications made to the Intra-Operative Positioning System do not raise new or different questions of safety or effectiveness. The successful completion of non-clinical testing demonstrates that the Intra-Operative Positioning System performs as intended and is substantially equivalent to the predicate device.