February 17, 2026

Centerline Biomedical, Inc.
Carroll Martin
Sr. Regulatory Affairs Manager
4535 Renaissance Pkwy.
Cleveland, Ohio 44128

Re: K254089
Trade/Device Name: IOPS Visionary™
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQY, DQX
Dated: December 19, 2025
Received: December 19, 2025

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Aneesh S. Deoras -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.	K254089

Please provide the device trade name(s).

IOPS Visionary™

Please provide your Indications for Use below.

The IOPS Visionary 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 (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary for the IOPS Visionary System

I. Device Name

Trade Name	IOPS Visionary™
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. Predicate Device

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

III. Device Description

The IOPS® Visionary 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). IOPS Visionary 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 IOPS Visionary System 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 IOPS Visionary System 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 (Interface Module, System Control Unit and Field Generator) and the accessories.

IV. Indications for Use

The IOPS Visionary 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.

V. Substantial Equivalence

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

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device IOPS Visionary System	Equivalence Discussion
Uninterruptible power supply (UPS)	Provides power when electricity is not available	Provides power when electricity is not available.	Same
Power Requirements	120V, 60HZ	120V, 50/60HZ	Different. The addition of 50Hz enables the device to work with European standard electrical frequencies. This difference does not have any impact to safety or effectiveness
Voltage Transformer	Not present	Present	Different. This component allows the operation of the device with European 230V power input. This difference does not have any impact on safety or effectiveness.
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 up to two onboard monitors and provide a video signal for an external display.	Different. This allows more than one user to observe the procedure. This does not impact the safety or effectiveness of the device.
Cables	Allows data transfer	Allows data transfer	Same

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device IOPS Visionary System	Equivalence Discussion
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.	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. Allows for overlay of live fluoroscopic imaging to the rendered vascular map.	Different. The additional capability for allowing for the overlay of live fluoroscopic imaging is a convenience to the user. Live imaging allows the user to take into consideration any changes to the patient that have occurred since the original preoperative CT scan or the intra-operative conebeam scan was taken.
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.	Same

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device IOPS Visionary System	Equivalence Discussion
Sensor Interface Unit (SIU) (Renamed unit Interface Module for IOPS Visionary System)	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. The SIU (renamed the Interface Module) also serves as USB pass-through connection for Tableside Controls Unit	Different. This modification allows for communication between the Tableside Controls Unit and the IOPS device. This communication, in conjunction with the Tableside Controls Unit, allows the user to control the IOPS device from the Tableside Controls Unit. This modification does not affect the functionality, safety or effectiveness of the device.

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device IOPS Visionary System	Equivalence Discussion
Tableside Controls Unit (MDC)	Not present	Present.	Different. The addition of the Tableside Control Unit allows the clinician to have direct control over IOPS software display via surgical tableside-mounted hardware as opposed to having another person operate the device. The functions that the Tableside unit controls are controlled in the predicate via the keyboard and mouse. In this proposed device, these functions can be controlled either utilizing the keyboard and mouse or the Tableside unit. This is a convenience for the user. This modification does not affect the functionality, safety or effectiveness of the device.
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	Same

Device Features	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Intra-Operative Positioning System	Equivalence Discussion
Mounting brackets	Affixes field generator to operating table	Affixes field generator to operating table	Same
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.	Same
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-3) 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.	Same

Device Accessories	Predicate Device Intra-Operative Positioning System, K243842	Subject Device 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).	Same
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.	Same

Device Accessories	Predicate Device Intra-Operative Positioning System, K243842	Subject Device Intra-Operative Positioning System	Equivalence Discussion
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.	Same
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.	Same

VI. Performance Testing

System and software verification and validation testing was conducted to establish equivalency to the predicate device in safety and effectiveness and to ensure the IOPS Visionary System met established requirements.

VII. Animal and Clinical Testing

No animal or clinical testing was conducted.

VIII. Conclusions

The differences between the IOPS Visionary System and its predicate do not raise new or different questions of safety or effectiveness. The successful completion of non-clinical testing demonstrates that the IOPS Visionary System performs as intended and is substantially equivalent to the predicate device.