July 24, 2024

Centerline Biomedical, Inc.
Amanda Shade
Sr. Regulatory Affairs Manager
10000 Cedar Ave
Cleveland, Ohio 44106

Re: K241243
Trade/Device Name: Intra-Operative Positioning System (IOPS®) Viewpoint (Simple Curve Catheters); Intra-Operative Positioning System (IOPS®) Viewpoint (Double Curve Catheters)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQY
Dated: June 21, 2024
Received: June 24, 2024

Dear Amanda Shade:

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.

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

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)*

K241243

Device Name

Intra-Operative Positioning System (IOPS®) Viewpoint (Simple Curve Catheters);
Intra-Operative Positioning System (IOPS®) Viewpoint (Double Curve Catheters)

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."

510(k) #: K241243

510(k) Summary

Prepared on: 2024-06-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Centerline Biomedical, Inc.
Applicant Address	10000 Cedar Ave Cleveland OH 44106 United States
Applicant Contact Telephone	216-206-7364
Applicant Contact	Amanda Shade
Applicant Contact Email	amanda@centerlinebiomedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Intra-Operative Positioning System (IOPS®) Viewpoint (Simple Curve Catheters); Intra-Operative Positioning System (IOPS®) Viewpoint (Double Curve Catheters)
Common Name	Programmable diagnostic computer
Classification Name	Computer, Diagnostic, Programmable
Regulation Number	870.1425
Product Code(s)	DQK, DQY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190106	IOPS Simple Curve Catheter and IOPS Reverse Curve Catheter	DQK
K230309	IOPS Simple Curve Catheter and IOPS Reverse Curve Catheter	DQK

Device Description Summary

21 CFR 807.92(a)(4)

The IOPS Viewpoint Catheters are sterile, single use 6 Fr catheters intended for use with the Intra-Operative Positioning System (IOPS), manufactured by Centerline Biomedical. They are designed to be inserted into the femoral artery, brachial artery, or axillary artery and navigate through vasculature in the descending aorta to access branch vessels near to, or involved in, the lesion during endovascular procedures.

The IOPS Viewpoint Catheters are available in two tip shape configurations (Simple and Double). Each tip shape is available in two lengths (75cm and 125cm). All models are 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. The catheters have a radiopaque marker near the distal tip and a luer locking hub on the proximal end.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the IOPS Viewpoint Catheters have not changed from the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate devices are intended for use with the Intra-Operative Positioning System. The principles of operation of IOPS Viewpoint Catheters remain unchanged from the predicate devices. Both devices are compatible with 0.035" IOPS guidewire. The following technological differences exist between the subject and predicate devices:
-The subject devices have a smaller OD (6 Fr) in comparison to the predicate devices (8 Fr).
-The subject devices have different working length (75cm and 125cm) and overall length options (85cm and 135cm) in comparison to the predicate devices (100cm working length and 105cm overall length).
-The subject devices have different distal tip shapes, angles, and forming process in comparison to the predicate devices.
-The subject devices have longer signal cable and smaller size EM Sensors in comparison to the predicate devices.
-The subject devices include a radiopaque marker near the distal tip.
-The subject devices have some different materials used in the construction of catheters.
-The subject devices are packaged in a tray system and Tyvek pouch while the predicate devices are packaged in a mounting card and Tyvek pouch.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Testing:
The following tests were conducted on the IOPS Viewpoint Catheters to establish equivalency to the predicate device in safety and effectiveness:
• Evaluation per ISO 10555-1 for peak tensile force, freedom from leakage, radio-detectability, hubs, and visual inspection of surface/ distal tip
• Dimensional analysis
• Simulated use in an abdominal aorta model
• Sensor functionality, placement, and accuracy
• Hub to connector cable bond
• Particulate testing per USP <788>
• Radiopacity per ASTM F640
• Accuracy testing with IOPS per ASTM F2554
• IEC 60601 and Applied Part Testing
• Hub compliance with ISO 80369
• Biocompatibility per ISO 10993
• Sterilization per ISO 11135 and ANSI/AAMI TIR 28
• EO/ECH residuals per ISO 10993-7
• Bacterial endotoxins per USP <85>
• Simulated distribution per ISTA Procedure 3A and ASTM D4169
• Packaging integrity per ASTM F2096 and ASTM F88/F88M

Conclusion:
The subject devices have similar technological characteristics and the same indications/intended use as the predicate devices. The differences in technological characteristics do not raise new or different questions of safety or effectiveness. The successful completion of non-clinical testing demonstrates that the IOPS Viewpoint Catheters perform as intended and are substantially equivalent to the predicate.