October 11, 2024

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

Re: K242133
Trade/Device Name: Intra-Operative Positioning System (IOPS®) (Fiducial Tracking Pad); Intra-Operative Positioning System (IOPS®) (Guidewire Handle)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 19, 2024
Received: July 22, 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.

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

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)*

K242133

Device Name

Intra-Operative Positioning System (IOPS®) (Fiducial Tracking Pad);
Intra-Operative Positioning System (IOPS®) (Guidewire Handle)

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.

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510(k) #: K242133

510(k) Summary

Prepared on: 2024-09-11

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®) (Fiducial Tracking Pad); Intra-Operative Positioning System (IOPS®) (Guidewire Handle)
Common Name	Programmable diagnostic computer
Classification Name	Computer, Diagnostic, Programmable
Regulation Number	870.1425
Product Code(s)	DQK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190106	Intra-Operative Positioning System (IOPS): Tracking Pad; Guidev	DQK
K230309	IOPS Tracking Pad (TP-1); IOPS Guidewire Handle (SSH-1)	DQK

Device Description Summary

21 CFR 807.92(a)(4)

IOPS Fiducial Tracking Pad is a sterile, single use tracking pad intended for use with the Intra-Operative Positioning System (IOPS), manufactured by Centerline Biomedical. It is equipped with a single tracking sensor allowing IOPS to track gross patient motion to allow maintenance of patient registration during a 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.

IOPS Guidewire Handle is a sterile, single use, non-sensorized device intended for use with the Intra-Operative Positioning System (IOPS) and its sensorized 0.035" guidewire, manufactured by Centerline Biomedical. It is meant to be connected 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.

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 IOPS Fiducial Tracking Pad and IOPS Guidewire Handle 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 Fiducial Tracking Pad and IOPS Guidewire Handle remain unchanged from the predicate devices. The subject devices have a longer shelf life and a different packaging system than the predicate device. Both the subject and predicate devices are sterilized by ethylene oxide gas but the sterilization method was changed from established category A to established category B.

The following technological differences apply to the IOPS Fiducial Tracking Pad and its predicate:
- The subject device is smaller in size than the predicate device.
- The subject device utilizes a different EM sensor than the predicate device.
- The subject device has less quantity of EM sensors and fiducials than the predicate device.
- The subject device contains a printed circuit board and a longer signal cable than the predicate device.
- Some materials used in the construction of the subject device are different from the predicate device.

The following technological differences apply to the IOPS Guidewire Handle and its predicate:
- The subject device is smaller in size than the predicate device.
- The subject device does not have a metal shielding while the predicate does.
- The subject device contains a printed circuit board and a longer signal cable than the predicate device.
- Some materials used in the construction of the subject device are different from the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Testing:
The following tests were conducted on the IOPS Fiducial Tracking Pad and IOPS Guidewire Handle to establish equivalency to the predicate device in safety and effectiveness:
• Dimensional Analysis
• Device Functionality and Essential Performance
• Tensile
• Radiopacity
• Accuracy Testing with IOPS per ASTM F2554
• IEC 60601 and Applied Part Testing
• Biocompatibility per ISO 10993
• Sterilization per ISO 14937 and TIR56
• EO/ECH Residuals per ISO 10993-7
• Packaging Integrity per ISO 11607
• Design Validation

Conclusion:
The subject devices have similar technological characteristics and the same indications/intended use as the predicate device. 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 Fiducial Tracking Pad and IOPS Guidewire Handle perform as intended and are substantially equivalent to the predicate.