June 21, 2023

Centerline Biomedical, Inc.
Amanda Shade
Sr. Quality & Regulatory Manager
1000 Cedar Avenue
Cleveland, Ohio 44106

Re: K230309
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
Dated: May 19, 2023
Received: May 22, 2023

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230309

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 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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004. 510(k) Summary

As required by section 807.92(c)

Centerline Biomedical Inc. is requesting marketing clearance for the labeling modification of the Intra-Operative Positioning System (IOPS®) previously cleared under K190106.

A. Submitted By: Centerline Biomedical, Inc.
10000 Cedar Avenue
Cleveland, OH 44106
Registration Number: 3012154226

B. Date: May 19, 2023

C. Contact Person: Amanda Shade, Sr. Quality & Regulatory Manager
Contact Telephone: (216) 206-7364

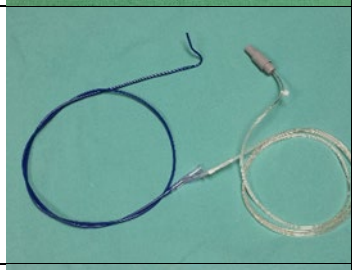
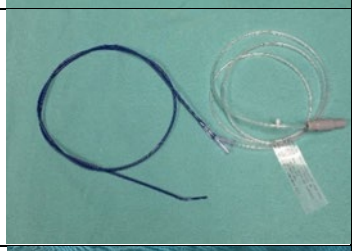
D. Device Trade Name: Intra-Operative Positioning System (IOPS®)
Device Classification Name: Programmable diagnostic computer (21 CFR 870.1425)
Device Classification: Class II
Reviewing Panel: Cardiovascular
Product Code: DQK

E. Predicate Device: Intra-Operative Positioning System (IOPS) (K190106)

F. Device Description:
The IOPS system 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.

Sub-system	Identification	Function	Picture
Reusable Components	Mobile Cart (MC-1)	Stores all components when not in use; provides system mobility	
	Onboard Monitor	Displays patient maps and superimposed images	
	Computer	Provides an operating system	
	Keyboard	Allows data input	
	Mouse	Allows data input	
	Uninterruptible power supply (UPS)	Provides power when electricity is not available	

Sub-system	Identification	Function	Picture
			
	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.	
	Cables	Allows data transfer	
	IOPS Software Application	Software which creates vascular map used to show location of sensorized catheter and guidewires real time. Vascular map is generated from a preoperative CT scan which is processed to segment the vasculature and perform centerline and surface analysis.	
	System Control Unit (SCU)	Collects information from the SIUs, calculates the position and orientation of each sensor and interfaces with the host computer.	
	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	
	Electromagnetic Field Generator	Emits a low-intensity, varying electromagnetic field and establishes the position of the tracking volume	

Sub-system	Identification	Function	Picture
	Mounting brackets	Affixes field generator to operating table	
Single Use Sterile Accessories (All cleared per K190106)	Guidewire (ATW-2)	Sensorized wire used to navigate through vasculature to facilitate placement of a catheter	
	Reverse Curve Catheter (RCC-1)	Sensorized tube used to navigate through vasculature	
	Simple Curve Catheter (SCC-1)	Sensorized tube used to navigate through vasculature	
	Tracking Pad (TP-1)	Pad that registers patient movement	
	Guidewire Handle (SSH-1)	Provides interface between the sensorized guidewire and the SIU	

Principle of Action:

The system is intended for use by trained clinicians for patients undergoing endovascular interventional procedures of the descending aorta, such as stent grafting. The system promotes more efficient use of operating room time and minimizes the need for fluoroscopy. The clinician uses the IOPS catheters and guidewires to navigate through the aorta to access branch vessels near to, or involved in, the lesion. The catheters and guidewires are not for angiographic or diagnostic use.

The main principles of action for the IOPS are similar to those used in Global Positioning System (GPS) tracking. The navigation components generate a time-varying magnetic field in which the position and orientation of sensor embedded catheters and guidewires are read. The computing unit visually displays the location of the sensor on the patient's vascular map.

Embedded sensors are located in the tip of the IOPS catheter and guidewire. When the sensor enters the electromagnetic field, small voltages are induced in the sensor coils. The size of the voltage depends on the location of the sensor coil in the overall EM field. Transformations are induced, which are combinations of translation and rotation values that describe the position and orientation of the embedded sensors. The data is transferred via cables to a sensor interface unit (SIU), which digitizes the sensor data and transmits it to the system control unit (SCU). The SCU calculates a 5DOF (degrees of freedom) transformation for each sensor producing X,Y,Z, pitch and yaw location information. Data is transferred via cables to the system control unit (SCU) and processed with proprietary software to generate the sensor location which is transposed onto the patient's vascular map.

The patient's vascular map is generated using a contrast enhanced, high resolution CT scan (up to 6 months prior to the procedure) which is part of the standard care of patients undergoing endovascular interventional procedures. The IOPS creates a 3D rendering of that structure. A bone segmented 3D rendering is also created to provide anatomical, skeletal points visible in relation to the vascular rendering.

Before the patient is placed on the OR table, a tracking pad embedded with sensors is affixed to the small of the back in a location proximate to the volume of interest. The tracking pad corrects for patient movement and ensures the overlay of the live tracking to the previously acquired vascular map is aligned. By correlating the vascular rendering, the position of the tracking pad, and its relation to the same fiducial points, the sensor locations are superimposed on the vascular rendering with a position error of approximately ±1 mm. Because the human aorta is approximately 25 mm in diameter and the branch arteries are approximately 5-10 mm in diameter, this accuracy is sufficient to precisely position the catheter and guidewire tips within an artery.

The mobile IOPS is brought into the operating room, wheels are locked, and the power cable is plugged into a 120V wall outlet. The IOPS is powered on and an Ethernet port is connected to the hospital's picture archiving and communication system (PACS), if desired. Alternatively, data can be imported/exported using a USB drive.

The electromagnetic field generator is affixed to the underside of the patient table and the SIU is attached to the side rail of patient table approximately 1 meter from the field generator. After the

patient is placed on the OR table, a cone beam CT (CBCT) is acquired using fluoroscopy with a flat panel detector (FPD). The scan is uploaded to the hospital's PACS. The CBCT is registered to the initial CT using the IOPS software and the 3D renderings.

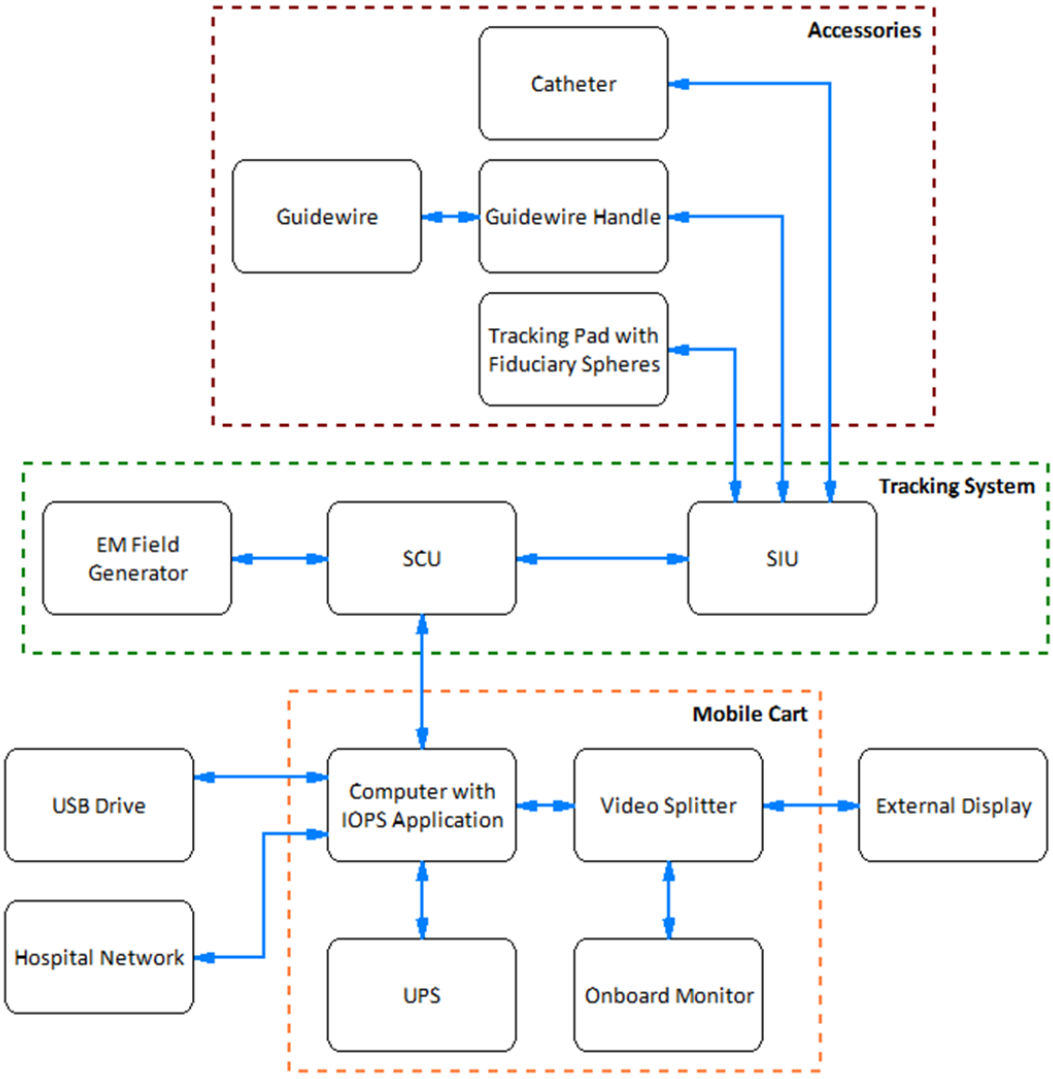
During the procedure, the surgeon observes the movement of the sensors within the catheter and guidewire on the 3D rendering of the vasculature. The rendering can be rotated and manipulated allowing the surgeon to view branch vessel ostia in three dimensions from an optimal view angle.

Component Description:
The IOPS mobile cart houses a monitor, computer, keyboard, pointing device, uninterruptable power supply (UPS), and cables. IOPS includes a tracking system composed of a system control unit (SCU), sensor interface unit (SIU), field generator, mounting brackets, and cables. These components are reusable and not patient contacting.
The IOPS includes proprietary software used to generate the 3D rendering of the vascular structure from data collected from the patient scans. The software generates the patient's vascular model which is displayed on the monitor of the IOPS and collects data provided by the SCU of the tracking system. The software overlays the sensor position from the tracking system data on to the patient's 3D vascular map. The software enables the user to view the 3-D rendered image from any direction and zoom in and out. The software notifies the user of errors or degraded accuracy. The software corrects for patient motion. The software operates in one of two modes: live recording and playback simulation. The live recording file is a combination of text markers, text values, and base-64 encoded data.

Navigation System:
The navigation system is a commercially available, advanced electromagnetic spatial measurement system purchased off-the-shelf from Northern Digital Imaging and is integrated into other cleared commercial devices. The Aurora® V3 System is designed to calculate the position and orientation of sensors within a defined volume to a high degree of accuracy. The Aurora® sensors are embedded into the IOPS catheter and guidewire.
The Aurora® system used in IOPS includes a windowed field generator, system control unit (SCU), sensor interface unit (SIU), and sensors which are embedded in disposable tools such as catheters and guidewires.
The catheter and guidewire are connected to the SIU which is connected to the SCU. When the embedded sensors are placed inside the electromagnetic detection region, a voltage is induced. The characteristics of the induced voltage depend on a combination of the sensor position and orientation and the strength and phase of the varying magnetic fields.
The SIU converts the voltages, induced in the sensors, to digital signals which are sent to the SCU.
The SCU controls the operation of the Aurora® System. It acts as an interface between the tracking system components and the CPU. The SCU supplies power to the field generator and controls the field generator's electromagnetic output. It collects sensor data via the SIU and calculates sensor positions and orientations, then sends the position and orientation data to the CPU.

The field generator provides a low-intensity (~100 micro-Tesla), varying electromagnetic field creating a volume in which sensor positions and orientations are read. The field generator is affixed to the operating room table with mounting brackets.
A system dedicated CPU, monitor, keyboard, and pointing device are housed within the IOPS cart. The computer uses transmission control protocol/internet protocol (TCP/IP) to communicate with the hospital's PACS, if desired, and houses the software used to create images and process the tracking system data. Alternatively, data can be imported/exported using a USB drive.
An uninterruptable power supply (UPS) is housed within the IOPS cart. In the event that power is not able to be supplied to the system, the UPS is able to power the IOPS for a minimum of 10 minutes.

Workflow of the system:



Single Use Sterile Accessories:

The accessories marketed with the Intra-Operative Positioning System (IOPS®) have been previously cleared under K190106 and the indications for use are consistent with the cleared indications.
The tracking pads are surface devices which contact intact skin for a duration of ≤ 24 hours. The catheters and guidewires are externally communicating devices which come in contact with circulating blood for duration of ≤ 24 hours.
The tracking pad is affixed to the small of the patient's back in a location proximate to the volume of interest. It is manufactured from Covestro Texin RxT70A polyurethane, Covestro Makrolon 2458 polycarbonate, and Vancive MED 5634 EVA foam with acrylic adhesive. Each registration marker contains three radio-opaque glass beads. The radio-opaque glass bead placement can be confirmed with fluoroscopy.
Guidewire handle connects to the 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.
Catheters and guidewires are inserted into the femoral artery, brachial artery, or axillary artery and navigate through the aorta to access branch vessels near to, or involved in, the lesion. Two types of catheters are offered with IOPS: a simple curve catheter and a reverse curve catheter.
Catheters, guidewires, tracking pads, and guidewire handles are provided sterile, pyrogen free, and intended for single use.

G. 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 descending aorta. The system is indicated for use as an adjunct to fluoroscopy. The IOPS does not make a diagnosis.

H. Technological Characteristics:

The intended use of the IOPS has not changed from the predicate device (IOPS 1.0). Minor changes to the hardware were introduced during IOPS 1.2 to support obsolescence of old computer components (e.g., motherboard, video card, and monitor), a new keyboard/mouse, and the addition of an HDMI splitter to support a second video output. The software was changed from version 1.0.5056 to 1.3.40.

I. Proposed Labeling:

The Intended Use of the modified device as described in its labeling has not changed. The proposed labeling changes include:

- Delete "WARNING: DO NOT place the IOPS equipment within 1 meter of RFID readers. There is a potential for electromagnetic interference which may affect the operation of the IOPS".
- Delete contraindication for use of IOPS on patients with pacemakers.
- Delete contraindication for use of IOPS with ICD (Implantable Cardioverter Defibrillator).
- Add warnings related to patients with pacemakers, implantable cardioverter-defibrillators (ICD), and cardiac implantable electronic devices (CIED).

- Delete “CAUTION: DO NOT use an external cardiac defibrillator on a patient while catheters and/or guidewires are inserted unless absolutely necessary (lifesaving)”.
- Change Applied Part designations from Type BF to Defibrillation-proof Type BF.

J. Non-clinical Testing:

Testing according to the following FDA-recognized consensus standards were performed on the Intra-Operative Positioning System to establish equivalency to the predicate device in safety and effectiveness:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- AIM 7351731 Rev. 2.00 (2017-02-23) - Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

K. Conclusion:

The completed testing associated with the proposed labeling changes has demonstrated that the subject device is substantially equivalent to the predicate device.