May 17, 2022

Centurion Medical Products
Sheri Deisler
Regulatory Affairs Manager
100 Centurion Way
Williamston, Michigan 48895

Re: K210548
Trade/Device Name: Medline Integrated Arterial Catheter
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 18, 2022
Received: April 18, 2022

Dear Sheri Deisler:

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,

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: 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)*
K210548/A001

Device Name
Medline Integrated Arterial Catheter

Indications for Use *(Describe)*
The Medline Integrated Arterial Catheter permits access to the peripheral arterial circulation system for short-term access (less than 30 days).

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.

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CENTURION
MEDICAL PRODUCTS

SECTION 5
510(k) Summary
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Centurion Medical Products
100 Centurion Way
Williamston, MI 48895
Registration Number: 3008403546

Contact Person(s)
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Summary Preparation Date
April 11, 2022

Type of 510(k) Submission
Traditional 510(k)

Device Name / Classification
Proprietary Name: Medline Integrated Arterial Catheter
Classification Name: Wire, Guide, Catheter
Product Code: DQX
Classification Panel: Cardiovascular
Regulatory Class: II
Regulation Number: 870.1330

CENTURION
MEDICAL PRODUCTS

Primary Predicate Device

Health Line ARTLINE
K160448

Secondary Predicate Device

Arrow Radial® Artery Catherization Set
K810675

Device Description

The Medline Integrated Arterial Catheter is a single-use device supplied sterile and non-pyrogenic; it will be packaged inside convenience kits alongside various components outside the scope of this 510(k) submission. The proposed device is a single lumen peripherally inserted catheter device designed to permit short-term access to the peripheral arterial circulatory for less than 30 days. The device assembly comprises a 20-Gauge catheter, 22-Gauge introducer needle, and a 0.018" guidewire with slide advancer. The catheter is made of radiopaque polyurethane tubing, echogenic needle, and removable stainless steel guidewire with slide advancer. The subject device has a kink-resistant catheter design. The device features dual flash with two distinct points of visualization, one with the clear introducer needle proximal hub and the second point at the notch cutout in the needle shaft. The final finished device is packaged with a suture wing (ALCS004). The suture wing is a Class I, 510(k) exempt device.

Principle of Operation

After puncturing the skin and advancement into the artery, arterial cannulation is verified visually by observing blood flashback into the catheter shaft and the clear hub of the introducer needle. The introducer needle is then advanced a maximum of 1-2 mm further into the vessel. The user stabilizes the introducer needle and then advances the guidewire using the actuating lever until it coincides with the clear tube's black indicator line. After that, the guidewire is deployed into the artery. The catheter is then advanced over the guidewire into the artery using a slight rotating motion. The catheter is held in place, and the assembly is then pulled back, removing the guidewire. After pulsatile blood flood is confirmed, a sterile primed hemodynamic monitoring tube with a stopcock is secured to the catheter tube. The catheter position is secured to the patient with a removable suture wing, provided with the proposed device and suture or a suture-free securement device per hospital protocol.

CENTURION
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Proposed Conditions of Use

An arterial catheter is intended for use in the general adult patient population. It is primarily used for real-time, dynamic monitoring of blood pressure in patients, including those experiencing shock, hypertensive emergency, stroke, patients on titratable vasoactive medications, and those undergoing complex surgical procedures. The device provides access for frequent blood draws, including ABG's in ventilated patients, and for monitoring cardiac function in conjunction with separate technologies (i.e., pulse pressure variation). The proposed device will be used in several hospital environments, including the ICU, OR, Anesthesiology, and Cath Lab. These environments will typically be well lit and climate-controlled. The Medline Integrated Arterial Catheter is a single-use device in which no re-use will occur, and sterile technique should be used during placement. The catheter may remain in place for up to 30 days and be utilized for continuous monitoring while therapy is being given or accessed intermittently for blood sampling.

Anatomical Location of Use and Description of Users

Arterial Catheters are inserted percutaneous into an artery (blood vessel); they are typically inserted into the radial artery but can be placed in the elbow (brachial), groin (femoral), or foot (Dorsalis pedis). Typical users of the proposed device include trained ICU physicians, intensivists, anesthesiologists, surgeons, and ICU nurses. Great care needs to be taken to avoid vessel wall puncture and inadvertent subarterial placement. Therefore, the intended users' will be nurses and physicians (e.g., anesthesiology, surgery, critical care) with education ranging from undergraduate to graduate level. Intended users should have basic knowledge and training of catheter placement techniques, contraindications, and necessary precautions. Intended users should have experience with the modified Seldinger technique, and only minimal device-specific training is needed (e.g., reading and understanding the IFU).

The Medline Integrated Arterial Catheter will be available as outlined below:

Centurion Medical Products Item Number	Description	Gauge	Length
RA20G175*	Medline Integrated Arterial Catheter	20Ga	1.75 inches

The final finished device, RA20G175, is packaged with a Suture Wing (ALCS004).

CENTURION
MEDICAL PRODUCTS

Indications for Use

The Medline Integrated Arterial Catheter permits access to the peripheral arterial circulation system for short-term access (less than 30 days).

Figure 1: Medline Integrated Arterial Catheter with protective tube (Photograph 1 of 3)

Figure 2: Medline Integrated Arterial Catheter (Photograph 2 of 3)

CENTURION
MEDICAL PRODUCTS

Figure 3: Suture Wing (Photograph 3 of 3)

The final finished device, RA20G175, is packaged with a Suture Wing (ALCS004), pictured above.

Summary of Technological Characteristics

The Medline Integrated Arterial Catheter is similar in design and technological characteristics to the predicate devices. Minor differences from the predicate devices design are minor and do not raise any additional questions on safety and effectiveness.

Table 5-1 provides a side-by-side comparison of the key attributes with the proposed device, the Medline Integrated Arterial Catheter, and the predicate devices, the Health Line ARTLINE (K160448), and the Arrow Radial® Artery Catherization Set (K810675).

CENTURION
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Table 5-1: Proposed and Predicate Device(s) Comparison

Device Characteristics	**Proposed Device** Medline Integrated Arterial Catheter	**Primary Predicate Device** Health Line ARTLINE	**Secondary Predicate Device** Arrow Radial ® Artery Catheterization Set	**Comparative Analysis**
Regulatory History	New Device	K160448	K810675	Same clearance pathway
Classification Panel	Cardiovascular	Cardiovascular	Cardiovascular	Same
Classification Name	Guide, Wire, Catheter	Guide, Wire, Catheter Catheter, Percutaneous	Guide, Wire, Catheter	Same
Device Class	Class II	Class II	Class II	Same
Device Code	DQX	DQX/DQY	DQX,	The proposed device and secondary predicate have the same device code. The primary predicate device has two product codes DQX/DQY.
Intended Use	The catheter is intended to permit access to peripheral vessels	The catheter is intended to permit access to peripheral vessels	The catheter is intended to permit access to peripheral vessels	Same
Indication for Use	The device permits access to the peripheral arterial circulation system for short-term access (less than 30 days).	The ARTLINE device permits access to the peripheral arterial circulation system for short-term access (less than 30 days).	The Arrow Arterial Catheterization device permits access to the peripheral arterial circulation or to other small vessels.	The indications for use are the same for the proposed device and primary predicate. The secondary predicate device varies slightly but still fall under the same intended use.

CENTURION
MEDICAL PRODUCTS

Device Characteristics	**Proposed Device** Medline Integrated Arterial Catheter	**Primary Predicate Device** Health Line ARTLINE	**Secondary Predicate Device** Arrow Radial ® Artery Catheterization Set	**Comparative Analysis**
Single Use Vs. Disposable	Single-Use	Single-Use	Single-Use	Same
Sterile Vs. Non-Sterile	Sterile	Sterile	Sterile	Same
Non-Pyrogenic	Yes	Yes	Yes	Same
Accessories	Suture Wing	Suture Wing	Suture Wing	Same
Available in Sterile Kit Configurations	Yes	Yes	Yes	Same
Sterilization Method	Ethylene Oxide Gas	Ethylene Oxide Gas	Ethylene Oxide Gas	Same
Shelf Life	1 Year	5 Year	Not indicated	N/A
Catheter body OD	20 Ga	20 Ga	18, 20 Ga	All three devices feature 20 Ga catheter body.
Catheter length	1 ¾ inches (4.45 cm)	1 ¾ inches (4.45 cm)	1 ¾ inches (4.45 cm)	Same
Catheter body material	Polyurethane	Polyurethane	Polyurethane	Same
Dual blood flashback	Yes – clear introducer needle proximal hub and notch cutout in the needle shaft	Yes – clear introducer needle proximal hub and notch cutout in the needle shaft	No - clear introducer needle proximal hub	The proposed device and primary predicate device feature dual flash. The secondary predicate device features one blood flashback.
Echogenic needle	Yes	Yes	Not indicated	The proposed device and primary predicate device feature an echogenic needle. The secondary

CENTURION
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Device Characteristics	**Proposed Device** Medline Integrated Arterial Catheter	**Primary Predicate Device** Health Line ARTLINE	**Secondary Predicate Device** Arrow Radial ® Artery Catheterization Set	**Comparative Analysis**
				predicate device does not have this feature.
Radiopaque single lumen catheter	Yes	Yes	Yes	Same
Integrated Guidewire	Yes	Yes	Yes	Same
Removable Guidewire	Yes	Yes	No	The proposed device and primary predicate device feature a removable guidewire. The secondary predicate device does not have this feature.
Kink Resistant	Yes	Yes	Yes	Same
Guidewire material/size	Stainless Steel 0.018", Straight, soft tip	Stainless Steel 0.018", Straight, soft tip	Stainless Steel 0.018", Straight, soft tip	Same

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Shelf Life and Sterilization

The Medline Integrated Arterial Catheter is sterilized by Ethylene Oxide (EO). The method used to validate the sterilization cycle for this device was conducted in accordance with ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices,* to ensure that a Sterility Assurance Level (SAL) of 1 x 10^{-6} is achieved. The proposed device has also been evaluated for EO/ECH residuals in accordance with ISO-10993-7:2008, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.*

In accordance with ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, aging studies have been conducted to verify a one-year shelf-life of the subject device and to ensure functionality and sterility are successfully maintained throughout the duration of this shelf life.

Summary of Testing

To evaluate performance and functionality, non-clinical verification of the Medline Integrated Arterial Catheter has been conducted. The results of these test have demonstrated the proposed devices' substantial equivalence in accordance with relevant test methods, and ultimately support a substantial equivalence determination.

Functional Performance Testing
Stress Cracking in accordance with ISO 80369-7
Positive Pressure Liquid Leakage in accordance with ISO 80369-7
Sub Atmospheric Pressure Air Leakage in accordance with ISO 80369-7
Resistance to Separation from Axial Load in accordance with ISO 80369-7
Resistance to Separation from Unscrewing in accordance with ISO 80369-7
Resistance to Overriding with ISO 80369-7
Kink Resistance
Bend Stiffness
Corrosion Resistance in accordance with ISO 11070
Guidewire Rebound
Peak Tensile Force in accordance with ISO 11070 and ISO 10555
Fracture in accordance with ISO 11070

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MEDICAL PRODUCTS

Flex in accordance with ISO 11070
Insertion Force
Loosening Force
Quick Flash
Strength of Union in accordance with ISO 11070
Visual Inspection
Simulated Use Testing
Print Durability
Freedom from Leakage in accordance with ISO 10555
Surface Inspection (Catheter Tube) in accordance with ISO 10555
Needle Bevel Interface Inspection in accordance with ISO 11070
Dimensional Verification
Echogenicity

Biocompatibility Testing

The biological evaluation of the subject device was conducted in accordance with *ISO 10993-1:2018 Biological Evaluation of the Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* as recognized by the FDA. The proposed device is classified an externally communicating device with prolonged duration of use (>24 hours, to ≤ 30 days) contact with circulating blood.

Summary of Clinical Testing

Not applicable. No clinical testing was conducted on the proposed device.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Centurion Medical Products concludes that Medline Integrated Arterial Catheter is substantially equivalent to the predicate device, Health Line ARTLINE (K160448).