March 30, 2018

Cook Incorporated
Reuben Lidster
Regulatory Affairs Specialist
750 Daniels Way P.O. Box 489
Bloomington, Indiana 47402

Re: K171988
Trade/Device Name: Performer Introducer and Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 27, 2018
Received: February 28, 2018

Dear Mr. Lidster:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171988

Device Name
Performer™ Introducer and Guiding Sheath

Indications for Use *(Describe)*
Performer™ Introducers and Guiding Sheaths are indicated for the percutaneous introduction of therapeutic or diagnostic devices to all heart chambers, including the left atrium via transseptal puncture.

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) SUMMARY -- K171899

Performer™ Introducer and Guiding Sheath
21 CFR §807.92
Date Prepared: February 27, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Reuben G. Lidster
Applicant Address:	Cook Incorporated
	750 Daniels Way
	Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104866
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Subject Device Information:

Trade Name:	Performer™ Introducer and Guiding Sheath
Common Name:	Catheter Introducer
Classification Name:	Catheter Introducer
Regulation/Product Code:	21 CFR §870.1340/DYB
Device Class/Panel:	Class II/Cardiovascular

Predicate Devices:

The HeartSpan® Fixed Curve Braided Transseptal Sheath (K132720) is the primary predicate device and the Arrow Transseptal Super Arrow-Flex® Percutaneous Sheath Introducer Set (K970229) is the secondary predicate device.

Subject Device Description:

The Performer™ Introducer and Guiding Sheath is manufactured using radiopaque fluorinated ethylene propylene (RFEP) tubing with a fluorinated ethylene propylene tungsten tubing (FETT) tip. The tip of the sheath is formed into various curves depending on the device configuration. The proximal end

consists of a hemostatic valve with a connecting tube and stopcock. The subject device is available with outside diameters ranging from 4 – 14 French and lengths ranging from 45 – 98 centimeters (smaller sizes sized for pediatric use and larger sizes for adults). The dilator is compatible with wire guides 0.025 – 0.038 inches in diameter. The supplied dilator is designed to extend beyond the tip of the sheath when the dilator is fully inserted through the hemostatic valve of the sheath. The Performer™ Introducer and Guiding Sheath is a sterile device intended for single use only.

Intended Use

The Performer™ Introducer and Guiding Sheath is indicated for the percutaneous introduction of therapeutic or diagnostic devices to all heart chambers, including the left atrium via transseptal puncture.

Comparison to the Predicates

The difference in the predicate devices indications for use and the subject device indications for use are in the specific wording in the indications for use statements. These statements differ slightly ("therapeutic or diagnostic devices" for the subject device as compared to "cardiovascular catheters" and "cardiovascular devices" for the primary and secondary predicate devices, respectively); however, the therapeutic or diagnostic devices that can be introduced through the subject device to the heart are intrinsically cardiovascular catheters. Accordingly, the two indications for use are substantially equivalent.

Furthermore, the subject device, the Performer™ Introducer and Guiding Sheath, is identical to the predicate devices, the HeartSpan® Fixed Curve Braided Transseptal Sheath (K132720) and the Arrow Transseptal Super Arrow-Flex® Percutaneous Sheath Introducer Set (K970229), in method of operation and fundamental technological characteristics. The subject device is similar in its design and materials to those of the predicate devices as well. These differences do not raise additional questions of safety or effectiveness.

Technological Characteristics:

The following tests were performed to demonstrate the Performer™ Introducer and Guiding Sheath met applicable design and performance requirements and these tests support a determination of substantial equivalence.

- Biocompatibility Testing – The following tests were performed in accordance with ISO 10993-1:2009 - cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity,

pyrogenicity, hemocompatibility, complement activation and partial thromboplastin time. The predetermined acceptance criteria were met.

- Age Testing - Performance testing was conducted on the Performer™ Introducers in accordance with BS EN ISO 11070:2014, after accelerated aging. The predetermined acceptance criteria for the respective testing were met.
- Dimensional Dilator Taper Extension Testing – The results verified, under the proper clinical use of the subject device, the dilator taper or the proximal edge of the dilator taper, will be in accordance with the applicable values of BS EN ISO 11070:2014, Annex A. The predetermined acceptance criterion was met.
- Dimensional Dilator Endhole Diameter Testing - The results verified, under the proper clinical use of the subject device, the dilator endhole will be in accordance with the specified tolerance. The predetermined acceptance criterion was met.
- Dimensional Dilator Hub Visual Testing - The results verified, under the proper clinical use of the subject device, the dilator hub will be in accordance with the specified tolerance. The predetermined acceptance criteria were met.
- Dimensional Stability and Compatibility Testing - The results verified, under the proper clinical use of the subject device, the dilator and sheath will be in accordance with the applicable values of BS EN ISO 11070:2014, Annex A or the specified tolerance. The predetermined acceptance criteria were met.
- Hub Testing - The results verified, under the proper clinical use of the subject device, the cannula hub will be in accordance with the applicable values of ISO-594-1 and ISO 594-2. The predetermined acceptance criteria were met.
- Liquid Leakage Testing – Test results verified, under proper clinical use of the subject device, there shall be no liquid leakage when tested in accordance with BS EN ISO 11070-1:2014, Annex D and/or E. The predetermined acceptance criteria were met.
- Rollback and Kink Testing – Test results verified, under proper clinical use of the subject device, there shall be no rollback and kink of the sheath when tested in accordance with BS EN ISO 11070, Annex A. The predetermined acceptance criteria were met.
- Tensile Testing of the female luer lock adaptor (FLLA) to Connecting Tube Joint – The results verified, under the proper clinical use of the subject device, the FLLA to connecting tube joint will be in accordance with the applicable values of BS EN ISO 11070:2014, Annex C. The predetermined acceptance criterion was met.
- Tensile Testing of the Dilator Hub to Shaft Joint – The results verified, under the proper clinical use of the subject device, the dilator hub to shaft joint will be in accordance with the applicable values of BS EN ISO 11070:2014, Annex C. The predetermined acceptance criterion was met.

- Tensile Testing of the Check-Flo Body to Shaft Bond – The results verified, under the proper clinical use of the subject device, the Check-Flo body and shaft bond will be in accordance with the applicable values of BS EN ISO 11070:2014, Annex C. The predetermined acceptance criterion was met.
- Tensile Testing of the Check-Flo Body to Connecting Tube Junction – The results verified, under the proper clinical use of the subject device, the Check-Flo body and connecting tube junction will be in accordance with the applicable values of BS EN ISO 11070:2014, Annex C. The predetermined acceptance criterion was met.
- Simulated Clinical Use Testing - The test articles were evaluated under conditions intended to simulate clinical use. All test articles evaluated met the predetermined acceptance criteria for all of the performance parameters.

Conclusion:

The subject device has indications for use and technological characteristics that are similar to the predicate devices. The results of the tests support the conclusion, the Performer™ Introducer and Guiding Sheath met the design input requirements based on the intended use. These results also support the conclusion that the intended use, design and material differences for the subject device, when compared to the predicate devices, the HeartSpan® Fixed Curve Braided Transseptal Sheath (K132720) and Arrow Transseptal Super Arrow-Flex® Percutaneous Sheath Introducer Set (K970229), do not raise new questions of safety or effectiveness.