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

February 16, 2021

Re: K203670
Trade/Device Name: Extra Large Check-Flo Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 17, 2020
Received: December 18, 2020

Dear Reuben 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. 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,

Finn Donaldson
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203670

Device Name
Extra Large Check-Flo® Introducer

Indications for Use *(Describe)*
Extra Large Check-Flo introducers and guiding sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature.

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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510(k) Summary

Extra Large Check-Flo® Introducer

Traditional 510(k) Summary

21 CFR §807.92(c)

Date Prepared: December 15, 2020

Submitter Information:

Applicant:	Cook Incorporated
Applicant Address:	750 Daniels Way
	Bloomington, IN 47404
Contact:	Reuben G. Lidster
Email:	RegSubmissions@cookmedical.com
Contact Phone Number:	812-335-3575 x 104866 or 812-325-4172
Contact Fax Number:	(812) 332-0281

Subject Device Information:

Trade Name:	Extra Large Check-Flo® Introducer
Common Name:	Introducer, Catheter
Classification Name:	Catheter Introducer
Classification Regulation:	21 CFR §870.1340, Product Code DYB
Device Class/Classification Panel:	Class II, Cardiovascular

Predicate Device:

The GORE® DrySeal Sheath (K093791) was cleared for commercial distribution on March 22, 2010.

Reference Devices:

The GORE® DrySeal Flex Introducer Sheath (K160254) was cleared for commercial distribution on May 12, 2016. The reference device offers additional working lengths (33, 45 and 65 cm), compared to the predicate (28 cm only).

The Medtronic Sentrant Introducer Sheath with Hydrophilic Coating (K171866) was cleared for commercial distribution on December 20, 2017. The reference device offers comparative characterization testing for the dilator removal force.

Subject Device Description:

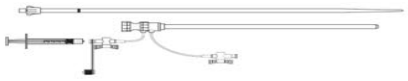
Cook Incorporated's Extra Large Check-Flo® Introducer is a single-use, sterile, disposable product that is used to introduce therapeutic or diagnostic devices into the vasculature. The Extra Large Check-Flo® Introducer consists of an introducer sheath, Check-Flo® hemostatic valve assembly, and dilator. The sheath is constructed with a hemostatic valve that accepts a large range of French sizes while preventing blood reflux and air aspiration. The subject device, the Extra Large Check-Flo® Introducer, is manufactured in diameters of 20.0, 22.0 and 24.0 French with sheath lengths of 25, 40, or 65 centimeters. The dilator is manufactured in lengths 16 centimeters longer than the sheath (41, 56, and 81 centimeters, respectively). The diameter of the distal endhole of the dilator measures 0.035 inch. The introducer sheath and dilator are matched as a unit to provide a smooth transition.

Intended Use:

Extra Large Check-Flo introducers and guiding sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature.

Comparison to the Predicate Device:

The Extra Large Check-Flo® Introducer, subject of this submission, is substantially equivalent to the predicate device, the GORE® DrySeal Sheath (K093791), in that these devices have the same general intended use, design, fundamental technological characteristics, and method of operation. The following table offers a comparison of different aspects of the subject and predicate device:

	PREDICATE DEVICE	SUBJECT DEVICE
	GORE DrySeal Sheath	**Extra Large Check-Flo Introducer**
Regulation Number	870.1340	870.1340
Product Code	DYB	DYB
Classification	Class II	Class II
Indications for Use	The GORE® DrySeal Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.	Extra Large Check-Flo introducers and guiding sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature.
Image		
Introducer Sheath		
Tubing	Polyethylene	Thick Wall Sheathing Radiopaque Tetrafluoroethylene (VRTS)
Introducer Sheath Size (Fr)	12.0, 14.0, 16.0, 18.0, 20.0, 22.0, 24.0, and 26.0	20.0, 22.0, and 24.0
Introducer Sheath Length (Working Length) (cm)	28	25, 40, and 65
Tip Shape	Straight	Identical
Check-Flo Assembly		
Connecting Tube (Material)	Unknown	Non-di(2-ethylhexyl) phthalate (DEHP) Polyvinyl Chloride (PVC) & PVC
Stopcock	Unknown	Polycarbonate and Polyethylene
Check-Flo Body	Unknown	Polycarbonate
Check-Flo Valve	Silicone	Silicone
Check-Flo Cap	Unknown	White Polyacetal
Dilator		
Shaft	Unknown	Vinyl Radiopaque Dilator Tubing (VRDT)
Hub	Unknown	Polyacetal
Introducer Dilator Size (Fr)	Unknown	20.0, 22.0, 24.0
Introducer Dilator Length (cm)	Unknown	41, 56, and 81
Dilator Endhole Diameter (in)	0.035	Identical

Test Data:

The subject device, the Extra Large Check-Flo® Introducer, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests performed are listed below:

- Biocompatibility - Per ANSI AAMI ISO 10993-1, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility were performed to ensure the biocompatibility of the subject device. Test results indicated that all materials are biocompatible.
- Tensile Testing - Tested in accordance with the requirements of BS EN ISO 11070. Test results met predetermined criteria.
- Compatibility Testing – Tested in accordance with the requirements of BS EN ISO 11070. Test results met predetermined criteria.
- Integrity Testing – Testing verified that, under proper clinical use of the subject device, the sheath tip exhibited no visible damage, including cracks, splits, and rollback. Upon withdrawal of the dilator, the sheath remained patent and unwrinkled. Test results met predetermined criteria.
- Rollback Testing – Tested in accordance with BS EN ISO 11070, Annex A. The predetermined acceptance criterion was met.
- Radiopacity Evaluation - Tested in accordance with ASTM F640-12. Test results met predetermined criteria.
- Dilator Removal Force Testing – The force to remove the dilator from the sheath met the specification and was comparable to the reference device (K171866).
- Dimensional Testing – Effective product dimensions derived from the manufacturing specifications were confirmed.
- Simulated Use Testing – Subject device tested through an anatomical model to test the subject device's reliability in a clinical simulated use scenario.
- Valve Leakage – Tested in accordance with the acceptance criterion established in BS EN ISO 11070.

Conclusion:

The results of the tests support the conclusion that, the Extra Large Check-Flo® Introducer met the design input requirements based on the intended use. Further, these results also support the conclusion that the design and material differences for the subject device, when compared to the predicate device, the GORE® DrySeal Sheath (K093791), support a conclusion that the Extra Large Check-Flo Introducer, subject of this submission, met the design input requirements based on the device's intended use and that it is substantially equivalent to the predicate device.