June 4, 2018

Cook Incorporated
Jennifer Allman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K171609
Trade/Device Name: Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 3, 2018
Received: May 4, 2018

Dear Jennifer Allman:

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 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,

Kenneth J. Cavanaugh -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171609

Device Name
Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set

Indications for Use *(Describe)*
The Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set is intended to introduce diagnostic and interventional devices in radial artery access procedures.

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 **K171609**

Submitted By:

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Phone: (812) 335-3575 x104280
Fax: (812) 332-0281
Date Prepared: May 30, 2018

Device:

Trade Name:	Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set
Common Name:	Catheter Introducer
Classification Name:	Introducer, Catheter DYB (21 CFR §870.1340)

Indications for Use:

The Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set is intended to introduce diagnostic and interventional devices in radial artery access procedures.

Predicate Device:

The predicate device for this submission is the Cook Incorporated Flexor® Radial Hydrophilic Introducer Access Set cleared for commercial distribution under 510(k) number K152044, on August 14, 2015.

Comparison to Predicate Device:

It has been demonstrated that the Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set is comparable to the predicate device (K152044) in terms of intended use, principles of operation, and basic technological characteristics. The subject device provides additional lengths, fewer diameters, and differing materials as compared to the predicate device (K152044). Additionally, the subject device includes wire guides with differing materials and dimensions as compared to the predicate device. The substantial equivalence of the subject device to the predicate device is supported by performance and biocompatibility testing.

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Device Description:

The Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set is a Class II device according to 21 CFR §870.1340; product code DYB (Catheter Introducer). The Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set is composed of an introducer sheath and dilator. The subject device also includes additional procedural components such as a wire guide and a 21 gage needle with a 4 inch length. Some subject device configurations also include a luer locking syringe. Table 1 of this 510(k) Summary provides a product matrix of the subject device components. The Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set is intended to introduce diagnostic and interventional devices in radial artery access procedures.

Table 1: Dimensional Variants of the Subject Device

Introducer Outside Diameter (French)	Introducer Length (cm)	Dilator Tip Inside Diameter (inches)	Wire Guide (cm)	
			Diameter (inches)	Length (cm)
4.0	5.5	0.018	0.018	30
	13		0.018	40
	23		0.018	40
5.0	5.5	0.018	0.018	25
	7		0.018	30
	13		0.018	40
	23		0.018	80
6.0	5.5	0.018	0.018	25
	7		0.018	25
	13		0.018	40
	23		0.018	80

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Table 2: Comparison of Technological Characteristics

Technological Characteristic		PREDICATE DEVICE	SUBJECT DEVICE
		Flexor Radial Hydrophilic Introducer Access Set (K152044)	Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set
Introducer			
Outside Diameter (French)	**Length (cm)**		
4.0	5.5		X
4.0	7	X	
4.0	13	X	X
4.0	23	X	X
5.0	5.5		X
5.0	7	X	X
5.0	13	X	X
5.0	23	X	X
6.0	5.5		X
6.0	7	X	X
6.0	13	X	X
6.0	23	X	X
7.0	13	X	
7.0	23	X	
Check-Flo Valve Assembly		X	X
Wire Guide			
Diameter (inch)			
0.018		X	X
Needle			
Diameter (gage)			
21		X	X

The Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set is a packaged, sterile device intended for single patient use.

There are no prior submissions for the subject device.

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Test Data:

The Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Biocompatibility Testing – Testing was performed in accordance with BS EN ISO 10993-1:2009, the materials and methods used to manufacture the subject device are non-toxic and met the predetermined acceptance criteria for their intended use.
- Dimensional Stability – Dimensional Stability and Compatibility Testing of the Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set was performed in accordance with an approved study protocol. The predetermined acceptance criteria were met.
- Dilator and Introducer Sheath Tensile Testing – Tensile testing verified that under proper clinical use of the dilator and introducer sheath, the peak load values shall be in accordance with BS EN ISO 11070:2014, Annex C. The predetermined acceptance criteria were met.
- Liquid leakage under pressure – Leakage testing verified that under proper clinical use the Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set shall not leak when tested in accordance with an approved study protocol. The predetermined acceptance criteria were met.
- Valve leakage testing under pressure testing – Valve leakage testing verified that under proper clinical use the Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set shall not leak past the hemostasis valve when tested in accordance with ISO 11070 Annex E. and an approved study protocol. The predetermined acceptance criteria for the respective testing were met.
- Rollback and Kink Resistance – Insertion testing of the Cook Inc. Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set in accordance with ISO 11070:2014, Annex A verified that under proper clinical use of the dilator and introducer sheath, each test article shall show no signs of damage such as rollback or cracks at the tip and/or signs of kinking of the shaft. The predetermined acceptance criteria for the respective testing were met.

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- Age Testing – Performance testing was conducted on aged Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set devices in accordance with BS EN ISO 11070:2014. The predetermined acceptance criteria for the respective testing were met.
- Acute Performance – Acute Performance Evaluation of the Check-Flo® Performer™ Introducer Micropuncture® Radial Artery Access Set was performed in an animal model. The predetermined acceptance criteria were met.

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.