DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 14, 2015

Cook Incorporated
Sarah Reeves
Regulatory Engineer
750 Daniels Way, P.O. Box 489
Bloomington, IN, 47402

Re: K152044
Trade/Device Name: Flexor Radial Hydrophilic Introducer Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: II
Product Code: DYB
Dated: July 22, 2015
Received: July 23, 2015

Dear Ms. Reeves:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K152044

Device Name: Flexor® Radial Hydrophilic Introducer Access Set

Indications for Use for the Flexor® Radial Hydrophilic Introducer Access Set:

The Flexor® Radial Hydrophilic Introducer Access Set is intended to introduce diagnostic and interventional devices in radial artery access procedures.

Prescription Use __X__ OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) SUMMARY

Submitted By: Sarah Reeves
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750 Daniels Way
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Phone: (812) 335-3575 x105024
Fax: (812) 332-0281
Date Prepared: July 22, 2015

Device:

Trade Name:	Flexor® Radial Hydrophilic Introducer Access Set
Common Name:	Introducer Set
Classification Name:	Catheter, Introducer
	DYB (21 CFR §870.1340)

Indications for Use:

The Flexor® Radial Hydrophilic Introducer Access Set is intended to introduce diagnostic and interventional devices in radial artery access procedures.

Predicate Device:

The device, subject of this submission, is substantially equivalent to the predicate device of identical name, the Flexor® Radial Hydrophilic Introducer Access Set, cleared under 510(k) number K132592.

Comparison to Predicate Device:

It has been demonstrated that the Flexor® Radial Hydrophilic Introducer Access Set is comparable to the predicate device. The Flexor® Radial Hydrophilic Introducer Access Sets are identical in terms of intended use, principles of operation, basic technological characteristics, and

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materials of construction, with the exception of the check-flo valve, to the predicate device. The check-flo valve has been modified in response to physician feedback. The safety and effectiveness of the modifications are supported by testing.

Device Description:

The Flexor® Radial Hydrophilic Introducer Access Set is an introducer set, supplied with an introducer sheath, dilator, wire guide and access needle. The introducers are available in whole French sizes from 4.0 through 7.0 French and in lengths of 7, 13 and 23 centimeters. The sets are compatible with the supplied 0.018" wire guide. The sets are supplied sterile and intended for one-time use.

Test Data:

The following tests were performed to demonstrate that the Flexor® Radial Hydrophilic Introducer Access Set met applicable design and performance requirements and support a determination of substantial equivalence.

- Acute Performance – Testing performed verified that performance parameters were acceptable for clinical use. The predetermined acceptance criterion was met.
- Check-Flo valve liquid leakage testing – Testing verified that the Check-Flo valve will not experience excessive leakage when utilized according to the device's intended use. The predetermined acceptance criteria were met.
- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogen, hemocompatibility, complement activation, partial thromboplastin time, and thromboresistance) demonstrated the device as biocompatible. In conformance with the applicable sections of ISO 10993-1:2009, the predetermined acceptance criteria were met.

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