



Food and Drug Administration  
10903 New Hampshire Avenue  
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March 7, 2016

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

Re: K153430

Trade/Device Name: Flexor Tuohy-Borst Side-Arm Introducers Shuttle Select  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter Introducer  
Regulatory Class: II  
Product Code: DYB  
Dated: February 9, 2016  
Received: February 10, 2016

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" (21CFR 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,

**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

## Indications for Use

510(k) Number (if known)

K153430

Device Name

Flexor Tuohy-Borst Side-Arm Introducers Shuttle Select

Indications for Use (Describe)

Flexor® Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro 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.

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## 510(k) SUMMARY

K153430

**Submitted By:** Sarah Reeves  
Cook Incorporated  
750 Daniels Way  
P.O. Box 489  
Bloomington, IN 47402  
Phone: (812) 335-3575 x105024  
Fax: (812) 332-0281  
Date Prepared: 09 February 2016

### Device:

**Trade Name:** Flexor<sup>®</sup> Tuohy-Borst Side-Arm Introducers  
Shuttle Select<sup>®</sup>  
**Common Name:** Introducer Set  
**Classification Name:** Introducer, Catheter  
DYB (21 CFR §870.1340)

### Indications for Use:

Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

### Predicate Device:

The device, subject of this submission, is substantially equivalent to the predicate device, Cook Incorporated Shuttle<sup>®</sup>-SL Flexor<sup>®</sup> Tuohy-Borst Side-Arm Introducer cleared for commercial distribution under 510(k) number K142819 on 24 July 2015.

### Comparison to Predicate Device:

It has been demonstrated that the Flexor<sup>®</sup> Tuohy-Borst Side-Arm Introducers Shuttle Select<sup>®</sup> are comparable to the predicate device. The subject device is identical to the predicate in terms of intended use, principles of operation and basic technological characteristics to the predicate device. Additional shaft materials have been included. The substantial equivalence of the modifications is supported by testing.



## **Device Description:**

The Flexor<sup>®</sup> Tuohy-Borst Side-Arm Introducers Shuttle Select<sup>®</sup> are composed of an introducer sheath and a dilator. These devices will be manufactured in 5.0 and 6.0 French and in a length of 90 cm.

## **Test Data:**

The following tests were performed to demonstrate that the Flexor<sup>®</sup> Tuohy-Borst Side-Arm Introducers met applicable design and performance requirements and support a determination of substantial equivalence.

- Acute performance – Testing verified that performance parameters were acceptable for clinical use. The predetermined acceptance criterion was met.
- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, hemocompatibility, complement activation, and partial thromboplastin time) demonstrated that the device is biocompatible. In conformance with the applicable sections of AAMI/ANSI/ISO 10993-1:2009, the predetermined acceptance criteria were met.
- Coating integrity and device compatibility testing under simulated use – Testing verified that the coating appearance was absent of defects before and after simulated use.
- Dilator and introducer sheath liquid leakage – Testing verified that under proper clinical use of the dilator and introducer sheath, each test article shall not leak when tested in accordance with BS EN ISO 11070:1999, Annex D and E. The predetermined acceptance criteria were met.
- Dilator and introducer sheath lubricity – Testing verified that, while hydrated and subjected to a 300 gram normal force, the peak force over a 10 centimeter stroke shall be less than 100 grams during the course of 10 cycles. The predetermined acceptance criteria were met.
- Dilator and introducer sheath tensile testing – Testing verified that under proper clinical use of the dilator and introducer sheath, the peak load values shall be in accordance with the applicable values of BS EN ISO 11070:1999. The predetermined acceptance criteria were met.
- Dimensional verification testing – Testing verified component compatibility and dimensional tolerances.



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- Thromboresistance testing – Testing verified that there would be 0% to 25% estimated patency impact due to thrombus associated with the test articles. The predetermined acceptance criterion was met.
- Torque strength testing – Testing verified that under proper clinical use, the device could withstand one full rotation without failure.

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