



Food and Drug Administration
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April 29, 2015

Cordis Corporation
Michelle Ragozzino Rodgers, Ph.D.
Senior Regulatory Affairs Specialist
6500 Paseo Padre Parkway
Fremont, California 94555

Re: K150836

Trade/Device Name: OUTBACK Elite Re-Entry Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: March 26, 2015
Received: March 30, 2015

Dear Dr. Ragozzino Rodgers:

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,

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)

K150836

Device Name

OUTBACK Elite Re-Entry Catheter

Indications for Use (Describe)

The OUTBACK Elite Re-Entry Catheter is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The OUTBACK Elite Re-Entry Catheter is not intended for use in the coronary or cerebral 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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2. 510(k) SUMMARY

I. SUBMITTER

Cordis Corporation, a Johnson & Johnson Company
6500 Paseo Padre Parkway
Fremont, CA 94555

Contact Person: Michelle Ragozzino Rodgers, Ph.D.
Tel: (510) 248-2450
Fax: (510) 248-2533

Date Prepared: March 26, 2015

II. DEVICE

Name of Device: OUTBACK[®] Elite Re-Entry Catheter
Common Name: Percutaneous catheter
Classification Name: Catheter for Crossing Total Occlusions (21 CFR §870.1250)
Regulatory Class: Class II
Product Code: PDU

III. PREDICATE DEVICE

OUTBACK[®] LTD[™] Re-Entry Catheter, previously cleared on 1/13/2009 under K083814

IV. DEVICE DESCRIPTION

The OUTBACK[®] Elite Re-Entry Catheter is a single-use device designed to facilitate placement and positioning of guidewires within the peripheral vasculature. The device consists of three primary elements: 1) Cannula, 2) Catheter shaft, and 3) Deployment handle with deployment control slide. The OUTBACK[®] Elite Re-Entry Catheter is supplied sterile and is available in two useable lengths.

V. INDICATIONS FOR USE

The OUTBACK[®] Elite Re-Entry Catheter is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The OUTBACK[®] Elite Re-Entry Catheter is not intended for use in the coronary or cerebral vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The OUTBACK[®] Elite Re-Entry Catheter is identical to the predicate OUTBACK[®] LTD[™] Re-Entry Catheter in its basic design, intended use, Indications for Use statement, contraindications, mechanism of action, operating principle, sterilization method and Sterility Assurance Level (SAL). The changes to the subject device relative to the predicate are limited to a modified deployment handle, a modified packaging design, the addition of a shorter length device, and labeling updates. No modifications were made to the direct patient-contacting components (i.e.

the cannula and the catheter shaft) of the subject device other than the addition of a shorter length product code, in which catheter useable length is the only change. Other dimensional specifications, including the nosecone OD, catheter shaft OD, cannula reach, sheath compatibility and guidewire compatibility are identical to the predicate. Design verification and validation testing demonstrate that the catheter continues to meet all previous performance specifications and that none of the critical clinical performance parameters have changed.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

Biocompatibility testing was performed on finished and sterilized OUTBACK[®] Elite Re-Entry Catheters in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58 and per ISO 10993-1:2009/Cor 1:2010 Biological evaluation of medical devices - Part 1. Biocompatibility testing included the following:

- *In vitro* Cytotoxicity – MEM Elution
- *In vitro* Hemolysis - ASTM Extract & Direct Contact
- USP <661> Containers – Plastics, Physicochemical Tests

Device Dimensional and Functional Testing

- Device Joint Tensile Strength
- Catheter Torqueability
- Device Joint Torque to Failure

Packaging and Sterilization Testing

- Sterilization Validation
- Sterilization Loading Configuration Evaluation
- Bioburden
- EO residuals
- Bacterial Endotoxin
- NPRT
- D-Value
- Blue Dye Penetration
- Peel Strength

VIII. CONCLUSIONS

The subject OUTBACK[®] Elite Re-Entry Catheter is the same in basic design and has the identical intended use as the legally marketed predicate, OUTBACK[®] LTD[™] Re-Entry Catheter. The modifications made to the handle design and packaging and the addition of a shorter 80 cm

device do not alter the fundamental scientific technology of the device, the device's operating principles, mechanism of action, intended use, or the indication for use of the device. The design modifications made to the OUTBACK[®] Elite Re-Entry Catheter were verified and validated through a series of tests ensuring that the subject catheter meets all specifications and that the performance and functionality are substantially equivalent to the predicate device. The OUTBACK[®] Elite Re-Entry Catheter continues to meet all previous performance specifications and none of the critical clinical performance parameters have changed. The modifications do not raise new questions of safety and effectiveness. OUTBACK[®] Elite Re-Entry Catheter can be used according to its intended use and in an equivalent manner to the predicate device. The OUTBACK[®] Elite Re-Entry Catheter is substantially equivalent to the predicate OUTBACK[®] LTD[™] Re-Entry Catheter.