



Food and Drug Administration
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October 29, 2014

Covidien llc.
c/o Mark Job
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K142654

Trade/Device Name: Fortrex 0.035” OTW PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 16, 2014
Received: September 18, 2014

Dear Mr. Job:

This letter corrects our substantially equivalent letter of October 28, 2014.

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)

K142654

Device Name

Fortrex™ 0.035" OTW PTA Balloon Catheter

Indications for Use (Describe)

The Fortrex 0.035" OTW PTA Balloon Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Fortrex™ 0.035” OTW PTA Balloon Catheter
510(k) Summary**



510(k) Summary

Fortrex™ 0.035” OTW PTA Balloon Catheter

This 510(k) summary is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	Covidien llc 4600 Nathan Lane N Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Rupali Gupta Senior Regulatory Affairs Specialist
Date Prepared	August 25, 2014

2. Subject Device

Device Trade Name	Fortrex™ 0.035” OTW PTA Balloon Catheter
Device Common Name	PTA Dilatation Catheter
Classification Name	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR§870.1250, Product Code LIT
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	EverCross™ .035” OTW PTA Dilatation Catheter (Primary Predicate)
510(k) Number	K103322, K110319
510(k) Clearance Date	December 06, 2010, April 14, 2011
Device Trade Name	Mustang™ Balloon Dilatation Catheter
510(k) Number	K103751
510(k) Clearance Date	March 22, 2011

4. Device Description

The Fortrex™ 0.035” PTA Balloon Catheter (Fortrex Catheter) is an over the wire (OTW) 0.035” dual lumen catheter with a distally mounted semi-compliant inflatable balloon and an atraumatic tapered tip. The manifold includes a lumen marked “THRU”. This is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum diameter of 0.035”. The lumen marked “BALLOON” is the

Fortrex™ 0.035” OTW PTA Balloon Catheter 510(k) Summary



balloon inflation lumen, which is used to inflate and deflate the balloon with a mixture of contrast medium and saline solution. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating or working section of the balloon.

The Fortrex Catheter is available with balloon diameters 4.0 mm to 12.00 mm, balloon lengths 20 mm, 40 mm, 80 mm, and 100 mm and with shaft lengths of 40 cm, 80 cm, and 135 cm.

5. Indications for Use

The Fortrex™ 0.035” OTW PTA Balloon Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

6. Comparison of Technological Characteristics

The proposed Fortrex Catheter uses very similar design and materials as the primary predicate EverCross Catheter. Modifications have been made to the proposed Fortrex device design and materials to improve performance of the balloon through higher burst pressure and improved joint strength and integrity. The Fortrex Catheter shares the following similarities to the predicate devices:

- Similar fundamental scientific technology
- Same operating principle
- Similar balloon lengths
- Similar rated burst pressure

Additionally, the indications for use, device materials, and manufacturing site and methods are similar between the proposed Fortrex Catheter and the predicate EverCross Catheter.

7. Performance Testing Summary

To demonstrate substantial equivalence of the proposed Fortrex Catheter to the predicate EverCross device, bench testing and biocompatibility testing was performed. Results from these testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. Using internal Risk Analysis procedures, the following performance tests were performed:

Balloon Dimensional Verification	Device Tracking
Balloon Rated Burst Pressure	Insertion Force
Minimum Balloon Burst Strength	Balloon Pull-back Force
Balloon Fatigue	Reinsertion Force
Balloon Compliance	Torque Strength
Catheter Dimensional Verification	Tensile Strength
Inflation / Deflation Time	Kink
Wire Movement	Marker Band to Balloon Body
Radiopacity	

**Fortrex™ 0.035” OTW PTA Balloon Catheter
510(k) Summary**

The Fortrex Catheter was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). The testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, complement activation, thromboresistance, partial thromboplastin time, platelet/leukocyte counts, mutagenicity, lymphoma and micronucleus assay.

The Fortrex catheter met all acceptance criteria for the performance testing. The results from these tests demonstrate that the technological characteristics and performance criteria of the Fortrex Catheter are comparable to the predicate EverCross Catheter and that the Fortrex Catheter performs in a manner equivalent to the predicate EverCross device currently on the market.

8. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, Covidien considers the proposed Fortrex Catheter to be substantially equivalent to the currently marketed EverCross™ .035” OTW PTA Dilatation Catheter (K103322, K110319) and Mustang™ Balloon Dilatation Catheter (K103751).