K082529

NOV 20 2008

ev3®

# 510(k) Summary

## EverCross™ .035" OTW PTA Dilatation Catheter

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| **510(k) Summary** | This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92. |
| **Applicant** | ev3 Inc. |
| **Submitter** | ev3 Inc.<br>9600 54th Ave. N<br>Plymouth, MN 55442<br>Tel: 763-398-7000<br>Fax: 763-398-7200 |
| **Contact Person** | David Worrell, MS, RAC<br>Director, Regulatory Affairs |
| **Date Prepared** | September 3rd, 2008 |
| **Device Trade Name** | EverCross™ .035" OTW PTA Dilatation Catheter |
| **Device Common Name** | PTA Dilatation Catheter |
| **Classification Name** | Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 800.1250, Product Code LIT |
| **Classification Panel** | Cardiovascular |
| **Predicate Devices** | Sterling OTW PTA Balloon Dilatation Catheter (K053116), Admiral Xtreme PTA Balloon Catheter OTW .035 (K062809), Savvy Long and Sleek PTA Catheter (K072947), and Dorado PTA Balloon Dilatation Catheter (K072283). |
| **Intended use** | The EverCross .035" OTW PTA Dilatation 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. |
| **Device Description** | The EverCross Peripheral Dilatation 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 to aid in crossing tight stenoses. The distal catheter, proximal to the balloon, is covered with a hydrophilic coating. The catheter manifold includes two lumens. The lumen marked "THRU" is the central lumen of the |

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| | catheter which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum outer diameter of 0.035 inches. The lumen, marked "BALLOON" is used to inflate and deflate the dilatation balloon with a solution of contrast medium and saline. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. |
| **Performance data** | Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. |
| **Summary of Substantial Equivalence** | The EverCross .035" OTW PTA Dilatation Catheter has the following similarities to the predicate devices:<br>• Similar fundamental scientific technology (all predicates)<br>• Similar operating principle (all predicates)<br>• Similar balloon lengths (Savvy Long and Sleek K072947)<br>• Similar rated burst pressures (Dorado K072283). |
| **Conclusion** | Based on the similar indications for use, technological characteristics and performance testing, ev3 believes the EverCross .035" OTW PTA Dilatation Catheter is substantially equivalent to the Sterling OTW PTA Balloon Dilatation Catheter (K053116), the Admiral Xtreme PTA Balloon Catheter (K062809), the Savvy Long and Sleek PTA Catheters (K072947) and the Dorado PTA Balloon Dilatation Catheter (K072283). |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ev3 Inc.
c/o Mr. David Worrell
4600 Nathan Lane North
Plymouth, MN 55442-2920

NOV 20 2008

Re: K082579
EverCross 0.035" OTW PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (2)
Product Code: DQY
Dated: November 12, 2008
Received: November 13, 2008

Dear Mr. Worrell:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K082579

Device Name: EverCross™ .035" OTW PTA Dilatation Catheter

Indications for Use:

The EverCross 0.035" OTW PTA Dilatation 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.

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

**(Division Sign-Off)**
**Division of Cardiovascular Devices**
**510(k) Number** K082579