K090849

MAY - 1 2009

510(k) Summary

NanoCross™ .014" OTW PTA Dilatation Catheter

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.
Applicant	ev3 Inc.
Submitter	ev3 Inc. 9600 54th Ave N Plymouth, MN 55442 Tel: 763-398-7000 Fax: 763-398-7200
Contact Person	Sara Bakker Regulatory Affairs Specialist
Date Prepared	March 27, 2009
Device Trade Name	NanoCross™ .014" OTW PTA Dilatation Catheter
Device Common Name	PTA Dilatation Catheter
Classification Name	Catheter, Percutaneous (21 CFR 870.1250, Product Code DQY)
Classification Panel	Cardiovascular
Predicate Device	NanoCross™ .014" OTW PTA Dilatation Catheter (K082854)
Intended use	The NanoCross .014" 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.
Device Description	The NanoCross .014" OTW PTA Dilatation Catheter is an over the wire (OTW) 0.014" coaxial lumen catheter with a distally mounted semi-compliant inflatable balloon and an atraumatic, tapered tip. The distal portion of the catheter shaft and the balloon has a hydrophilic coating. The manifold includes a lumen marked "THRU". This is the central lumen of the catheter that terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum outer diameter of 0.014". 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. The radiopaque marker bands indicate the dilating or working section of the balloon. The 210mm balloon contains two additional radiopaque marker bands that denote the middle of the balloon body.
Performance data	Bench testing was 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.

K090849

Summary of Substantial Equivalence	The 210mm NanoCross .014" OTW PTA Dilatation Catheter has the following similarities to the legally marketed NanoCross .014" OTW PTA Dilatation Catheter: • Same indicated use, • Same operating principle, • Same device materials, • Same basic catheter design, • Same shelf life, • Same packaging and sterilization processes.
Conclusion	Based on the intended use, technological characteristics, safety and performance testing, the 210mm NanoCross .014" OTW PTA Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the legally marketed NanoCross .014" OTW PTA Dilatation Catheter (K082854).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

ev3 Inc.
c/o Ms. Sara Bakker
Regulatory Affairs Specialist
9600 54th Avenue North
Plymouth, MN 55442

Re: K090849
NanoCross .014" OTW PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: April 22, 2009
Received: April 23, 2009

Dear Ms. Bakker:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Donna R. Vachey

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): K090849

Device Name: NanoCross™ .014" OTW PTA Dilatation Catheter

Indications for Use:

The NanoCross 0.014" 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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)

Donna R. Vechman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090849