SEP - 8 2004

PREMARKET NOTIFICATION
510(k) SUMMARY
(Per 21 CFR Part 807.92)

Submitter's Name:	ev3 Inc.
Address:	4600 Nathan Lane North Plymouth, MN 55442 USA
Telephone No.:	763-398-7000
Facsimile No.:	763-398-7200
Contact Person:	Jill Munsinger
Date Summary Prepared:	June 9, 2004
Trade Name:	X-SIZER® Catheter System
Common or Usual Name:	Thrombectomy Device
Classification Name:	Catheter, Peripheral, Atherectomy (MCW) (21 CFR Part 870.4875)

Legally marketed devices to which ev3 Inc. claims substantial equivalence:

Edwards Lifesciences Thrombex PMT™ System	510(k) No. K993816
Solera Bacchus Thrombectomy Catheter (BTC)	510(k) No. K003570
Possis AngioJet® LF140 Catheter	510(k) No. K960970

Description of the device that is the subject of this Premarket Notification:
The X-SIZER System is a single-use, disposable medical device intended for the selective removal of thrombus from blood vessels. The device consists of a 135cm coaxial, dual lumen hydrophilic coated outer catheter shaft connected to a hand-held Control Module. The inner lumen of the catheter is composed of a hollow torque cable encapsulated in a polyamide tube (flexible drive shaft). A helical cutter is contained within the cutter housing located at the distal tip of the catheter. The outer lumen of the catheter is the path in which the excised debris is removed by vacuum. In use, the cutter is rotated at approximately 2,100 rpm by the motor, which is powered by a 9-volt alkaline battery. In addition to turning the helical cutter, the inner lumen provides the space through which a coronary guidewire is placed. The hand-held Control Module contains the motor, battery, circuitry, indicators, and various valves and manifolds for the vacuum removal of thrombotic debris. The X-SIZER System is available in the 1.5mm and 2.0mm diameter models.

Intended Use:
The X-SIZER Catheter System is indicated for the mechanical removal of thrombus in synthetic hemodialysis grafts.

Contraindications:
The X-SIZER Catheter System is contraindicated under the following circumstances and clinical conditions:

- Grafts that cannot be accessed with an 0.014" diameter guidewire.
- Grafts with reference diameters by visual estimation less than the minimum recommended diameters.
- A Prolonged Prothrombin Time (PPT) or Partial Prothrombin Time (PTT) or other documented anticoagulation state or disorder.
- Graft Infection
- Significant cardiopulmonary vascular compromise.
- Allergy or other contraindication to procedure related medications.

Technological Characteristics:
The X-SIZER Catheter System has the same technological characteristics as the predicate Edwards Lifesciences Thrombex PMT System, the Solera Bacchus Thrombectomy Catheter (BTC), and the Possis AngioJet LF140 Catheter. All of these devices, except the Possis AngioJet, use mechanical rotary motion to remove thrombotic materials from dialysis grafts. The X-SIZER Catheter System, the Thrombex PMT System, and the Possis AngioJet LF140 Catheter are constructed of stainless steel and PEBAX materials. All of the devices are designed for use over a guidewire and are packaged as sterile, single use devices.

Performance Data:
The X-SIZER Catheter System was subjected to *in vitro* bench tests including: basic functional operation, leak tests, battery life test, corrosion resistance, motor current and trackability test, hydrophilic coating test, flow rate test, device output test, kink resistance test, tensile tests, bond tests, joint tests, torque tests, flexibility (deflection) tests, shaft torque resistance, cutter/housing binding, and bench top thrombus cutting (extraction).

Comparative performance testing was performed with the X-SIZER Catheter System and a predicate device, the Edwards Lifesciences Thrombex PMT System, in a bench model simulating synthetic hemodialysis grafts. The X-SIZER Catheter System performed equivalently to the Thrombex PMT System when assessing clot extraction and safety within a synthetic graft material.

Additionally, the X-SIZER Catheter System and the predicate device, the Thrombex PMT System, were evaluated in an *in vivo* animal model utilizing thrombosed hemodialysis grafts. The X-SIZER System performed equivalently to the Thrombex PMT System when assessing vessel trauma, distal embolization, and overall device performance for the removal of thrombus in occluded dialysis grafts.

The results of the *in vitro* and *in vivo* tests performed demonstrate the device is as safe and effective as the legally marketed predicate devices.

Summary of Substantial Equivalence:
The X-SIZER Catheter System is substantially equivalent to the predicate Edwards Lifesciences Thrombex PMT System, the Solera Bacchus Thrombectomy Catheter (BTC), and the Possis AngioJet LF140 Catheter. The indications for use, principles of operation, methods of manufacture and materials are substantially equivalent to these legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

ev3, Inc.
c/o Ms. Brenda Johnson
Senior Regulatory Affairs Specialist
4600 Nathan Lane North
Plymouth, MN 55442

Re: K021096
X-SIZER
Regulation Number: 21 CFR 870.4875
Regulation Name: Catheter, Peripheral, Atherectomy
Regulatory Class: Class II
Product Code: MCW
Dated: June 9, 2004
Received: June 10, 2004

Dear Ms. Johnson:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochner

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): K021096

Device Name: X-SIZER® Catheter System

Indications For Use:

The X-SIZER Catheter System is indicated for the mechanical removal of thrombus in synthetic hemodialysis grafts.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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. Bochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K021096