AUG 1 1 2006

510(k) Summary
SpideRX™ Embolic Protection Device

510(k) Number: K062201

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

General Provisions:

Submitter's Name	**ev3** Inc. 4600 Nathan Lane North Plymouth, MN 55442
Official Contact:	Brenda Johnson Sr. Regulatory Affairs Specialist **ev3** Inc. 9600 54th Avenue North Plymouth, MN 55442 Tel: (763) 398-7238 Fax: (763) 398-7200 brenda.johnson@ev3.net
Trade Name:	SpideRX™ Embolic Protection Device
Common Name/Usual Name:	Embolic Protection Device
Classification Name:	Catheter, Percutaneous
Class:	Class II, 21 CFR 870.1250

Predicate Devices:

SpideRX Embolic Protection Device (K053195)

Device Description:

The SpideRX™ Embolic Protection Device is a percutaneously delivered distal embolic protection system that can be delivered over any 0.014" or 0.018" guidewire. The SpideRX Embolic Protection Device contains a Capture Wire composed of a nitinol mesh filter mounted on a convertible 190/320 cm PTFE-coated 0.014" stainless steel wire, and a dual-ended SpideRX Catheter for delivery and recovery.

Intended Use:

The SpideRX™ Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0 to 6.0 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral or peripheral vasculature.

Summary of Labeling Change:

The labeling has been modified to reflect use compatibility of the SpideRX Device with currently marketed drug-eluting stents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrat.
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Ms. Brenda Johnson
Senior Regulatory Affairs Specialist
ev3 Inc.
4600 Nathan Lane North
Plymouth, MN 55442-2920

Re: K062201
Trade/Device Name: ev3 Inc. SpideRX Embolic Protection Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Distal Embolic Protection Guidewire
Regulatory Class: Class II
Product Code: NFA
Dated: July 27, 2006
Received: August 1, 2006

Dear Ms. Johnson

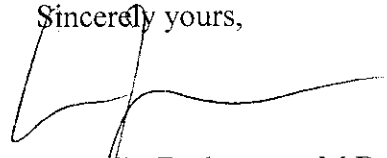
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 (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

510(k) Number (if known): K062201

Device Name: SpideRX™ Embolic Protection Device

Indications for Use:

The SpideRX Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0 to 6.0 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral or peripheral vasculature.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062201