FEB 1 7 2006

510(k) Summary
SpideRX™ Embolic Protection Device

510(k) Number: K052659

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

Submitter/Contact Person:

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Summary Preparation Date: September 22, 2005

Device Name and Classification:

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:

RX ACCUNET™ Embolic Protection System (K042218)
FilterWire EZ™ Embolic Protection System (K032884)

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 a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

Summary of Technological Characteristics:

The SpideRX Embolic Protection Device is a rapid exchange distal embolic protection device that is compatible with 0.014"/0.018" primary guidewires and utilizes a nitinol mesh filter to capture debris.

The delivery end of the SpideRX dual-ended Catheter is placed distal to the lesion by tracking over the primary guidewire. The primary guidewire is then removed and the SpideRX Capture Wire is advanced through the delivery end of the SpideRX Catheter. Filter deployment is accomplished by holding the SpideRX Capture Wire steady while pulling back and removing the SpideRX Catheter. When deployed, the nitinol mesh filter opens, apposes the vessel wall, and then acts as a strainer by capturing debris while allowing uninterrupted blood flow distally. The Capture Wire then functions as the guidewire while percutaneous transluminal angioplasty or stenting procedures are performed. Upon completion of the intervention, the recovery end of the SpideRX Catheter is advanced over the Capture Wire and the filter is recovered into the SpideRX Catheter, closing the filter and trapping the embolic debris inside the filter. The system is then removed.

The SpideRX Embolic Protection Device is substantially equivalent to the Guidant® RX ACCUNET™ Embolic Protection System (K042218) and the Boston Scientific FilterWire EZ Embolic Protection System (K032884) in regards to device design, principals of operation and materials. The SpideRX Embolic Protection Device is also substantially equivalent to the RX ACCUNET in intended use. The following features are the same or similar between the SpideRX Device and the predicate devices:

- Distal filter embolic protection
- Rapid-exchange devices
- Filter/basket component
- Compatible with 0.014" interventional devices
- Capture Wire accommodates both rapid exchange and over-the-wire PTA devices (FilterWire EZ and RX ACCUNET are available in both 190 and 300cm lengths, while SpideRX Device wire is 320cm in length, and snaps to 190cm to accommodate rapid exchange devices)
- Intended for use in similar vessel sizes
- Radiopaque guidewire tips and filter markers
- Radiopaque markers on sheath/catheter tips

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Comparisons of the SpideRX Device to the predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed RX ACCUNET and FilterWire EZ devices.

Summary of Testing:

Non-Clinical: *In vitro* testing of the SpideRX Embolic Protection Device consisted of biocompatibility, sterilization, packaging, product shelf life and performance testing. Functional performance testing was also completed in animal models. Test results verified that the SpideRX Device is adequate for its intended use. Additionally, the test results demonstrated that the SpideRX Device is equivalent to its predicate devices.

Clinical: The SpideRX Arm of the Carotid Revascularization with **ev3** Arterial Technology Evolution (CREATE) Trial was a non-randomized multi-center registry study that was performed to assess the safety and performance of the SpideRX Device when used with the commercially available ACCULINK™ Carotid Stent System. The differences observed between the primary endpoint event rates were not statistically significant, which demonstrate the safety and performance of the SpideRX Device for its intended use.

Statement of Equivalence:

The SpideRX Embolic Protection Device is substantially equivalent to the currently marketed RX ACCUNET™ Embolic Protection System (K042218) in intended use, materials, technological characteristics and performance. The SpideRX Embolic Protection Device is substantially equivalent to the FilterWire EZ™ Embolic Protection System (K032884) in materials, technological characteristics and performance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

ev3 Endovascular Inc.
c/o Mr. Glen D. Smythe
Senior Regulatory Affairs Specialist
4600 Nathan Lane North
Plymouth, MN 55442-2920

Re: K052659
SpideRX™ Embolic Protection Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: February 10, 2006
Received: February 13, 2006

Dear Mr. Smythe:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman 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): _____

Device Name: SpideRX™ Embolic Protection Device

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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)

ion Sign-Off)
ion of Cardiovascular Devices
k) Number K052659