510(k) Summary
JUN 2 3 2006

SpideRX™ Embolic Protection Device

510(k) Number: K053195

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

Submitter/Contact Person:

Submitter's Name:

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Summary Preparation Date: May 11, 2006

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:

FilterWire EZ™ Embolic Protection System (K032884)
GuardWire® Plus Temporary Occlusion and Aspiration System (K023878)

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 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 Boston Scientific FilterWire™ EZ Embolic Protection System (K032884) in regards to device design, principals of operation and materials. Additionally the SpideRX Embolic Protection Device is substantially equivalent to the FilterWire EZ and Medtronic/PercuSurge® GuardWire® Plus Temporary Occlusion and Aspiration System (K023878) in intended use.

The following features are the same or similar between the SpideRX Device and the FilterWire EZ:

- 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 is 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

The following features are the same or similar between the SpideRX Device and the GuardWire:

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

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 FilterWire EZ and GuardWire 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 clinical evaluation of the SpideRX Embolic Protection Device was performed through the SPIDER (Saphenous Vein Graft Protection In a Distal Embolic Protection Randomized) Trial. The SPIDER Trial was a prospective, randomized, multi-center trial in which a total of 963 patients were enrolled (747 in the randomized portion). During the trial, a rapid exchange design of the SPIDER Embolic Protection Device, the SpideRX™ Embolic Protection Device, was incorporated into the trial. The SPIDER Trial randomized 383 patients to the SPIDER/SpideRX Device Arm and 364 patients to the Control Arm (FilterWire EX™ Embolic Protection System, FilterWire EZ™ Embolic Protection System or GuardWire® Plus Temporary Occlusion and Aspiration System).

The primary endpoint, 30-day MACE, was 9.2% for the Treatment Group and 8.7% for the Control Group. In the Treatment Group there was one death, 33 myocardial infarctions, four target vessel revascularizations and no emergent CABG procedures. In the Control Group there were two deaths, 27 myocardial infarctions, four target vessel revascularizations and no emergent CABG procedures. The non-inferiority hypothesis of Treatment when compared to Control required that the difference in the thirty-day MACE rate between the two groups be statistically significantly less than the delta of 5.5%. The observed

difference between the Treatment and Control Groups was 0.5%, with a one-sided upper confidence limit of 4.1%, which is less than the delta of 5.5%. Using the Farrington-Manning approach, the null hypothesis was rejected with the p-value = 0.012, and thus the Treatment Group was concluded to be non-inferior to the Control Group with the delta of 5.5%.

During the conduct of the SPIDER trial, there were 133 Treatment subjects and 126 Control subjects who had at least one missing CK-MB result with the remaining CK-MB results being <3x normal range; there were four Treatment subjects and five Control subjects with missing CK-MB at all three time points (6-8, 12-16, and 18-24 hours post procedure). To address this issue of missing CK-MB data, additional analysis on MACE was preformed. To estimate what the non Q wave MI rate would have been for these missing patients had their missing CK-MB(s) been measured, the following analysis was preformed. Data from the SPIDER trial with non-missing CK-MB at all three time points (6-8, 12-16, and 18-24 hours post procedure) were used to statistically estimate, for each of the SPIDER trial subjects with missing CK-MB, the probability that at least one missing CK-MB was abnormal ($\geq$ 3x normal range). The probabilities were then summed to obtain an estimate of the number of missing CK-MB subjects who would have had an abnormal CK-MB and hence non-Q wave MI. Therefore, based on an analysis of data within the SPIDER trial of all subjects with CK-MB values at all three time points, we estimate that 2 to 3 additional subjects in each group would have experienced non-Q wave MIs, and, hence, MACE. The following table displays results of revised MACE analyses where 3 additional MACE are added to each group with recalculation of the non-inferiority hypothesis using the Farrington-Manning p value. In order to provide an even more conservative estimate of non-inferiority, the table also includes the calculation where 3 patients are added to the Treatment group and either 2 or 0 patients are added to the Control group.

As can be seen, there is no marked change in results from the primary analysis with any of these approaches in that non-inferiority according to the protocol criteria is met.

Table 1 - Revised MACE Analysis

	SPIDER	Control	Delta	p*
30-day MACE[1]	37/368 (10.1%)	33/345 (9.6%)	5.5%	0.013
30-day MACE[2]	37/368 (10.1%)	32/345 (9.3%)	5.5%	0.018
30-day MACE[3]	37/368 (10.1%)	30/345 (8.7%)	5.5%	0.031

[1] 3 additional MACE imputed for Treatment group and 3 additional MACE imputed for Control.
[2] 3 additional MACE imputed for Treatment group and 2 additional MACE imputed for Control.
[3] 3 additional MACE imputed for Treatment group and 0 additional MACE imputed for Control.
* Farrington-Manning

Statement of Equivalence:

The SpideRX™ Embolic Protection Device is substantially equivalent to the currently marketed Boston Scientific FilterWire™ EZ Embolic Protection System (K032884) in regards to intended use, materials, technological characteristics and performance. Additionally, the SpideRX Embolic Protection Device is substantially equivalent to the FilterWire EZ and the Medtronic/PercuSurge® GuardWire® Plus Temporary Occlusion and Aspiration System (K023878) in clinical performance of embolic protection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

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

Re: K053195
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: May 22, 2006
Received: May 23, 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,

Donna R. Volmer

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): K053195

Device Name: SpideRX™ Embolic Protection Device

Indications for Use:

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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)

Donna R. Bachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053195