

DEC 19 2003

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Embolectomy Catheter

Product Trade Name: PRONTO Extraction Catheter

Classification Name: Unclassified
Product Code, DXE

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Establishment Registration: 2134812

Contact: Gregory Sachs
Director of Regulatory Affairs
(763) 656-4210 phone
(763) 656-4253 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:

The Pronto extraction catheter is a dual lumen catheter with related accessories. The extraction lumen allows for the aspiration and removal of emboli/thrombi using the included syringe, extension line and stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate advancement of the catheter into the blood vessel and maximize extraction of emboli/thrombi through the extraction lumen. Incorporated within the catheter distal tip is a non-blood contacting radiopaque marker for fluoroscopic visualization. The catheter is a monorail design with a distal flexible region and a proximal stiff region. The distal portion of the catheter is coated with Tween (Polysorbate 80); this coating is to lubricate the catheter for ease of use. The catheter has an approximate outer diameter of 0.065 inches, allowing delivery through standard 6Fr. guide catheters. The smaller wire lumen of the catheter is able to accommodate guide wires that are ≤ 0.014 " in diameter. The catheter will be available in working lengths of 40 to 145 cm, in increments of 15 cm. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of the catheter to the included extension line, stopcock, and syringe. A 74 micron filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis of thrombus.

Intended Use:

The Pronto Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Summary of Non-Clinical Testing:

Testing conducted included assessments of the design verification of the Pronto Extraction Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Pronto Extraction Catheter for its intended use.

Summary of Clinical Testing:

No clinical evaluations of this product have been conducted.

Predicate Devices:

The intended use of the Pronto Extraction Catheter is similar to the intended use of the Fogarty Thru-Lumen Embolectomy Catheter, the American Biomed Embolectomy Catheter and the LeMaitre Embolectomy Catheter.

Conclusions:

The Pronto Extraction Catheter is substantially equivalent to the Fogarty Thru-Lumen Embolectomy Catheter, the American Biomed Embolectomy Catheter and the LeMaitre Embolectomy Catheter. The testing performed confirms that the Pronto Extraction Catheter will perform as intended.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Solutions, Inc.
c/o Mr. Gregory Sachs
Director of Regulatory Affairs
6464 Sycamore Court,
Minneapolis, MN 55369

Re: K032763
Vascular Solutions Pronto™ Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: 74 DXE
Dated: December 8, 2003
Received: December 9, 2003

Dear Mr. Sachs:

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.

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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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

