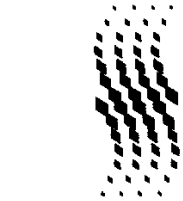
K072810



DEC 19 2007

510(k) SUMMARY

510(k) Number:_____

Date Prepared September 28, 2007

Submitter Information

Submitter's Name/ Address:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, MN 55369
Establishment Registration	2134812
Contact Person:	Doralie Poganski Director, Regulatory Affairs (763) 656-4307 telephone (763) 656-4200 fax dpoganski@vascularsolutions.com

Device Information

Trade Name:	Pronto™ Low Profile Extraction Catheter
Common Name:	Embolectomy Catheter
Classification Name:	Embolectomy Catheter
Product Code:	DXE
Regulation:	Class II, 21 CFR 870.5150

Predicate Device(s)

- Vascular Solutions Pronto™ V3 Extraction Catheter (K052232, K063371)
- Vascular Solutions QXT Extraction Catheter (K071727)
- Vascular Solutions Pronto™ Short Extraction Catheter (K051193)

Device Description

The Vascular Solutions Pronto™ Low Profile (LP) extraction catheter is a dual lumen catheter with related accessories. The Pronto LP will has a lower crossing

profile to provide compatibility with small vessels and deliverability through a standard 0.066" (6F) guide catheter alongside an additional 0.014" guidewire.

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 thrombus through the extraction lumen. Incorporated within the catheter distal tip is a non-blood contacting radiopaque marker for fluoroscopic visualization. The catheter has a rapid exchange design with a distal flexible region with stiffness along the shaft gradually increasing to the proximal region. The distal segment of the catheter that includes the guidewire lumen is coated with a hydrophilic coating to lubricate the catheter for ease of insertion.

The catheter also incorporates a Y-adapter with an aspiration port and a self sealing port with pre-loaded stylet. The stylet reinforces proximal shaft during delivery and is removed to allow aspiration of thrombus through the aspiration port.

Intended Use/Indications for Use

The Pronto LP extraction catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral system.

Summary of Non-Clinical Testing

Performance Testing: Device Verification Testing (DVT) was performed to support the equivalency of the Pronto LP extraction catheter to the predicate devices. DVT testing included:

- catheter tortuosity
- catheter curve retention
- catheter bond strength testing: hub, mid-shaft, and distal tip strength
- catheter leakage under pressure
- thrombus extraction
- blood extraction rate testing
- aspiration testing (with extension tube)
- packaging stylet removal force
- 2nd guidewire placement
- introducer passage
- catheter kink testing
- catheter deformation
- mandrel/wire removal
- guide catheter profile testing

The Pronto LP Extraction Catheter performance bench test results confirmed that the device performs as intended.

Biocompatibility: Biocompatibility testing in accordance with ISO 10993, "Biological Evaluation of Medical Devices" was provided. The material used in the Pronto LP extraction catheter has been demonstrated to be biocompatible.

The results of the testing provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

Summary of Clinical Testing

No clinical evaluations of this product have been conducted.

Statement of Equivalence

Through the data and information presented, Vascular Solutions considers the Pronto LP extraction catheter to be substantially equivalent to the Vascular Solutions Pronto™ Short Extraction Catheter, Vascular Solutions Pronto™ V3 Extraction Catheter, and the Vascular Solutions Pronto™ QXT Extraction Catheter. The testing performed confirms that the Pronto LP extraction catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2007

Vascular Solutions, Inc.
c/o Ms. Doralie Poganski
Director Regulatory Affairs
6464 Sycamore Court
Minneapolis, MN 55369

Re: K072810
Trade/Device Name: Pronto™ LP Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 21, 2007
Received: November 23, 2007

Dear Ms. Poganski:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

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