September 15, 2021

Vascular Solutions, Inc.
Patrice Stromberg
Sr. Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K070403
Trade/Device Name: Pronto .035" Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Patrice Stromberg:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 13, 2007. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 09:26:32 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2007

Vascular Solution, Inc.
c/o Ms. Patrice Stromberg
Sr. Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K070403
Pronto™ .035" extraction catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II (two)
Product Code: DXE
Dated: May 1, 2007
Received: May 24, 2007

Dear Ms. Stromberg:

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 Statement

510(k) Number (if known): K070403

Device Name: Pronto™ .035" Extraction Catheter

Indications for Use:

The Pronto .035" extraction catheter is indicated for:

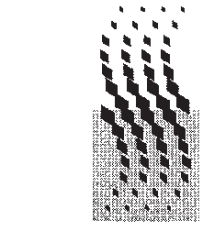
- The removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system.
- The removal/aspiration of embolic material (thrombus/debris) from vessels of the deep venous system.
- To infuse/deliver diagnostic or therapeutic agents.

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
510(k) Number K070403



JUN 13 2007

510(k) SUMMARY

510(k) Number: K070403

Date Prepared February 9, 2007

Submitter Information

Submitter's Name/ Address:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, MN 55369
Establishment Registration	2134812
Contact Person:	Patrice Stromberg Sr. Regulatory Affairs Associate (763) 656-4243 telephone (763) 656-4200 fax pstromberg@vascularsolutions.com

Device Information

Trade Name:	Pronto™ .035" 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™ Short Extraction Catheter (K051193)
- Lucas Medical, Inc. Thrombectomy Catheter (K970657)
- Edwards Lifesciences Fogarty Venous Thrombectomy Catheter (510k unknown)
- LeMaitre Vascular Inc. (formerly Vascutech, Inc.) LeMaitre Venous Thrombectomy Catheter (K992934)

Device Description

The Pronto .035" extraction catheter is a dual lumen, over-the-wire (OTW) catheter with related accessories. The catheter is designed to be delivered through a 10F or larger introducer sheath over a 0.035" guidewire. The larger lumen allows for the removal of thrombus by use of the included syringe through the extension line and stopcock. The catheter has a rounded distal tip with a protected, extraction lumen to facilitate advancement of the catheter into the blood vessel and maximize extraction of thrombus through the extraction lumen.

The catheter has a radiopaque marker band located approximately 4mm from the distal tip. The proximal end of the catheter incorporates a hemostatic Y-junction that allows for the attachment of the catheter to the included extension line, stopcock and syringe; and can be tightened down on the guidewire to prevent blood leakage.

Intended Use/Indications for Use

The Pronto .035" extraction catheter is indicated for:

- The removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system.
- The removal/aspiration of embolic material (thrombus/debris) from vessels of the deep venous system.
- To infuse/deliver diagnostic or therapeutic agents.

Summary of Non-Clinical Testing

Performance Testing: Device Verification Testing was performed to support the equivalency of the Pronto .035" extraction catheter to the predicate devices. Testing included mechanical, functional, shelf life and packaging testing. DVT testing included catheter tortuosity; catheter curve retention; catheter bond strength testing: hub and proximal shaft, proximal to mid-shaft, mid to distal shaft, and distal shaft to distal tip strength; catheter leakage under pressure; extension tubing to male luer strength; extension tubing to female luer strength; thrombus extraction; extraction rate testing; aspiration testing (with extension tube); saline injection test; contrast injection test; silicone visual inspection; packaging stylet removal force; guidewire passage; and introducer passage. The Pronto .035" extraction catheter met all specified design and performance requirements.

Biocompatibility. Biocompatibility testing in accordance with ISO 10993, "Biological Evaluation of Medical Devices" was provided. The material used in the Pronto .035" extraction catheter has been demonstrated to be biocompatible.

The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use. The Pronto .035" extraction catheter uses similar technology and has

similar intended uses, materials and dimensional characteristics to the predicate devices.

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 .035" extraction catheter to be substantially equivalent to the Vascular Solutions Pronto™ Short Extraction Catheter, Lucas Medical, Inc. Thrombectomy Catheter, Edwards Lifesciences Fogarty Venous Thrombectomy Catheter, and LeMaitre Vascular Inc. Venous Thrombectomy Catheter. The testing performed confirms that the Pronto .035" extraction catheter will perform as intended.