May 20, 2021

Vascular Solutions, Inc.
Charmaine Sutton
Acting VP Of Regulatory
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K083784
Trade/Device Name: Pronto V3 Extraction Center, Pronto LP Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Charmaine Sutton:

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 March 30, 2009. Specifically, FDA is updating this SE Letter as an administrative correction 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: 2021.05.20 09:35:42 -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

MAR 3 0 2009

Vascular Solutions, Inc.
c/o Ms. Charmaine Sutton, RAC
6464 Sycamore Court
Minneapolis, MN 55369

Re: K083784
Trade/Device Name: Pronto V3 extraction catheter, Pronto LP extraction catheter, Skyway RX support catheter, Skyway OTW support catheter, and Twin-Pass dual access catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE, DQY
Dated: March 16, 2009
Received: March 17, 2009

Dear Ms. Sutton:

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's) 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,

Donna R. Bohmer

Bram 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): K083784

Device Name: Skyway® OTW support catheter
Skyway® RX support catheter

Indications for Use:

The SKYWAY support catheter is intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The SKYWAY OTW also may be used to subselectively infuse/deliver 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Indications for Use

510(k) Number (if known): K083784

Device Name: Twin-Pass® dual access catheter

Indications for Use:

The TWIN-PASS dual access catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infusc/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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Indications for Use

510(k) Number (if known): K083784

Device Name: Pronto® V3 extraction catheter
Pronto® LP extraction catheter

Indications for Use:

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

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083784

K083784

3 510(k) Summary

MAR 3 0 2009

Date Prepared: December 18, 2008

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Charmaine Sutton, RAC
Acting VP of Regulatory
Tel: 763.656.4349 (direct); Fax: 763.656.4253
Email: csutton@vascularsolutions.com

General Information

Common Name (Classification)	Trade Name	Predicate Device
Embolectomy catheter (21 CFR 870.5150)	Pronto® V3 extraction catheter	K063371 Pronto V3 extraction catheter
	Pronto® LP extraction catheter	K072810 Pronto LP extraction catheter
Percutaneous catheter (21 CFR 870.1250)	Skyway® RX support catheter	K060327 Skyway RX support catheter
	Skyway® OTW support catheter	K060327 Skyway OTW support catheter
	Twin-Pass® dual access catheter	K060327 Twin-Pass dual access catheter

Device Description

The **Pronto V3 extraction catheter** is a dual lumen, hydrophilically coated, rapid exchange catheter with related accessories. The smaller wire lumen of the catheter is able to accommodate guidewires that are ≤ 0.014"/0.36mm in diameter. The larger extraction 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, 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. The proximal end of the catheter has a standard luer adapter that attaches to the included extension line, stopcock and syringes. The catheter has a working length of 140cm and is compatible with standard 6F guide catheters. A 70μm filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis of any thrombosis.

The **Pronto LP extraction catheter** is a dual lumen, hydrophilically coated rapid exchange catheter with related accessories. The smaller wire lumen of the catheter is able to accommodate guidewires that are ≤0.014"/0.36mm in diameter. The larger extraction lumen comes pre-loaded with a stylet that resists kinking during delivery but is removed to allow for the removal of

thrombus by aspiration. 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. The proximal end of the catheter has a Y-adapter hub containing a self-sealing stylet port, as well as a side-port for the attachment of the included extension line. The catheter has a working length of 137cm and is compatible with standard 6F guide catheters. A 70μm filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis of any thrombosis.

The **Skyway OTW (over-the-wire) and Skyway RX (rapid exchange) support catheters** are single lumen, hydrophilically coated catheters designed for use in the arterial vasculature. The catheters provide support for 0.014"/0.36mm guidewires during interventional procedures, and allow for the exchange of one distally located guidewire for another one while maintaining access to distal vasculature. The Skyway RX has a rapid exchange port that allows for the insertion of the catheter over a short guidewire; a stiffening mandrel provides support and pushability during catheter insertion.

The **Twin-Pass dual access catheter** is a hydrophilically coated, dual lumen catheter designed for use in the arterial vasculature. The catheter provides support for 0.014"/0.36mm guidewires during interventional procedures, and the dual lumen design allows for the delivery of a second guidewire into distal vasculature while leaving the initial guidewire in place. A stiffening mandrel provides support and pushability during catheter insertion.

Intended Use / Indications

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

The SKYWAY support catheter is intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The SKYWAY OTW also may be used to subselectively infuse/deliver therapeutic agents.

The TWIN-PASS dual access catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

Substantial Equivalence and Summary of Studies

Pronto, Skyway and Twin-Pass catheters are substantially equivalent in intended use / indications and design to their predicate devices. Hydrophilic coating design differences have been qualified through biomaterial assessments and verification testing, the results of which did not raise any new safety or performance questions.

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Sincerely yours,

Donna R. Bachner

Bram 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): K083784

Device Name: Skyway® OTW support catheter
Skyway® RX support catheter

Indications for Use:

The SKYWAY support catheter is intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The SKYWAY OTW also may be used to subselectively infuse/deliver therapeutic agents.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Indications for Use

510(k) Number (if known): K083784

Device Name: Twin-Pass® dual access catheter

Indications for Use:

The TWIN-PASS dual access catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively 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)

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(Posted November 13, 2003)

Indications for Use

510(k) Number (if known): K083784

Device Name: Pronto® V3 extraction catheter
Pronto® LP extraction catheter

Indications for Use:

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

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(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083784