December 1, 2017

Vascular Solutions Inc.
Becky Astrup
Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K173266
Trade/Device Name: Octane aspiration system
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: October 10, 2017
Received: October 11, 2017

Dear Ms. Astrup:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173266

Device Name
Octane Aspiration System

Indications for Use *(Describe)*
The Octane aspiration system is intended for the removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial and deep venous system, and to infuse/deliver diagnostic or therapeutic agents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K173266 **510(k) Summary**

[As required by 21 CFR 807.92]

Date Prepared: October 10, 2017

510(k) Number: K173266

Submitter's Name / Contact Person

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

Contact Person
Becky Astrup
Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-656-4253

General Information

Trade Name	Octane
Common / Usual Name	Aspiration system
Classification Name	DXE - Catheter, Embolectomy, Cardiovascular
Predicate	K112571 – Pronto XL extraction catheter – Vascular Solutions (October 6, 2011)
Reference Devices	K151313 – Zelante DVT thrombectomy set – Boston Scientific (September 21, 2015) K113757 – Aspire Max aspiration catheter - Control Medical Technology (February 22, 2012)

Device Description

The Octane aspiration system consists of two components: the Octane catheter and the Octane hand pump. The Octane aspiration catheter has a working length of 115cm, is compatible with introducer sheaths ≥ 8F, guidewires ≤ 0.018" in diameter, and it is intended for use in vessels ≥ 3 mm in diameter. The catheter has a rapid exchange design and includes sliding, co-axial inner and outer lumens. The catheter inner lumen tip has three side wall slot ports and the catheter's outer lumen has a beveled radiopaque tip. To alleviate plugging of the catheter tip caused by thrombus, the actuator on the proximal end of the catheter slides the catheter's outer lumen back and forth over the inner lumen distal tip. The actuator on the proximal end of the catheter is also used to control the directionality of the torque-able catheter. Directionality is further achieved through the gradual curve in the shaft materials at the distal end. The Octane hand pump provides suction to the inner lumen of the Octane aspiration catheter and is manually operated using a spring-loaded handle. It consists of a pump handle fitted with a 30ml piston syringe, tubing, a series of one-way valves, and a 500ml collection bag. The hand pump tubing has a standard luer fitting for connection to the Octane aspiration catheter hub. The Octane aspiration system has been sterilized with ethylene oxide.

Indications for Use

The Octane aspiration system is intended for the removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial and deep venous system, and to infuse/deliver diagnostic or therapeutic agents.

Technological Characteristics Comparison

The Octane aspiration system is similar in design and intended use to the predicate device, Pronto XL, as both are aspiration catheter systems intended for the removal of embolic material (thrombus/debris) from vessels of the arterial and deep venous system and to infuse/deliver diagnostic or therapeutic agents. The subject and predicate device are similar in size and working length. The materials used in the subject device are similar to the materials in the predicate device in that they are biocompatible, commonly utilized materials for interventional devices. The operating mechanisms of the Octane aspiration system are like those of the predicate, Pronto XL. The predicate Pronto XL device generates aspiration manually, through use of a piston syringe. Similarly, the Octane aspiration system generates aspiration manually, through use of a hand pump fitted with a piston syringe.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate device have been evaluated through biocompatibility and bench testing to provide evidence of Octane aspiration system substantial equivalence. The Octane aspiration system is substantially equivalent to the predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following tests:

- Track force
- Radiopacity
- Collection bag pressure
- Syringe seal attachment
- Check valve crack pressure
- Synthetic clot extraction
- Proximal seal leak
- Aspiration
- Liquid leak
- Bond/joint tensile
- Torque capacity
- Corrosion resistance
- Therapeutic agent conditioning
- Static pressure
- Package integrity

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Material mediated pyrogenicity
- Hemolysis
- Complement activation
- Thrombogenicity

The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Octane aspiration system is substantially equivalent to the predicate device.