September 11, 2018

Vascular Solutions, Inc.
Iroquois Ledbeter
Regulatory Product Specialist
6401 Sycamore Ct N
Maple Grove, Minnesota 55369

Re: K182232
Trade/Device Name: Octane Mechanical Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: August 16, 2018
Received: August 17, 2018

Dear Iroquois Ledbeter:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Gregory O'Connell
2018.09.11 16:02:05 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182232

Device Name

Octane Mechanical Thrombectomy System

Indications for Use *(Describe)*

The Octane Mechanical Thrombectomy 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.

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510(k) Summary

[As required by 21 CFR 807.92]

510(k) Number: K182232

SUBMITTER AND DEVICE

Submitter:
Vascular Solutions LLC
6464 Sycamore Court North
Minneapolis, MN 55369 USA

Establishment Registration: 2134812

Phone: 763-656-4300

Fax: 763-656-4253

Contact Person: Iroquois Ledbeter,
Regulatory Product Specialist

Date Prepared: August 16, 2018

Name of Device: Octane Mechanical Thrombectomy System

Common or Usual Name: Mechanical Thrombectomy System

Classification Name: DXE – Catheter, Embolectomy, Cardiovascular (21 CFR 870.5150)

Regulatory Class: II

Product Code: DXE

PREDICATE DEVICE

The legally marketed device to which substantial equivalence is claimed is:

Vascular Solutions Inc., Octane Aspiration System, K173266 cleared December 1, 2017.

DEVICE DESCRIPTION

The Octane Mechanical Thrombectomy System consists of two components: the Octane mechanical thrombectomy catheter and the Octane hand pump. The Octane mechanical thrombectomy catheter has a working length of 115cm, is compatible with introducer sheaths ≥ 8F 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 rapid exchange guidewire lumen is compatible with guidewires ≤ 0.018" in diameter and the 6F inner catheter lumen is compatible with guidewires ≤ 0.038" in diameter. 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 mechanical thrombectomy 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 mechanical thrombectomy catheter hub. The Octane Mechanical Thrombectomy System has been sterilized with ethylene oxide.

INDICATIONS FOR USE

The Octane Mechanical Thrombectomy 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Octane Mechanical Thrombectomy System is identical in design and intended use to the predicate device, the Octane Aspiration System. 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 identical in size and working length. The materials used in the subject device are identical to the materials in the predicate device. The operating mechanisms of the Octane Mechanical Thrombectomy System are identical to those of the predicate. The only difference between the subject and predicate device is labeling. The Octane Mechanical Thrombectomy System instructions for use includes an optional, alternate, technique for the deployment and removal of the Octane Mechanical Thrombectomy Catheter using the central extraction lumen of the device. This alternate technique allows for the catheter to be delivered and removed over guidewires ≤0.038" which provides the physician a benefit for ease of use.

PERFORMANCE DATA

There is no change or intended use or fundamental scientific technology between the subject and predicate devices. The following performance data were provided in support of the substantial equivalence determination.

Performance Testing - Bench

The technological differences between the subject and predicate device have been evaluated through bench tests to provide evidence that the subject device is substantially equivalent to the predicate device. The modifications to the device labeling are supported through concomitant device compatibility tests.

The results of the verification test met the specified acceptance criteria and did not raise different questions of safety and effectiveness.

CONCLUSION

The subject Octane Mechanical Thrombectomy System is equivalent to the Octane Aspiration System predicate devices based on comparisons of device functionality, technological characteristics, and indications for use. The results of design verification tests do not raise new or different questions of safety and effectiveness; therefore, the Octane Mechanical Thrombectomy System is substantially equivalent to the predicate device.