



Food and Drug Administration  
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August 11, 2016

Vascular Solutions, Inc.  
Adam Ettl  
Sr. Regulatory Product Specialist  
6464 Sycamore Court North  
Minneapolis, MN 55369

Re: K161336

Trade/Device Name: VSI StraitSet Micro-introducer Kit  
Regulation Number: 21 CFR 870.1310  
Regulation Name: Vessel Dilator for Percutaneous Catheterization  
Regulatory Class: Class II  
Product Code: DRE  
Dated: May 12, 2016  
Received: May 13, 2016

Dear Mr. Ettl:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Brian D. Pullin -S**

for Bram D. 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)

K161336

Device Name

VSI StraitSet micro-introducer kit

Indications for Use (Describe)

The VSI StraitSet micro-introducer kit is intended for use in percutaneous introduction and placement of catheters and guidewires.

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]

**Date Prepared:** 5/12/2016

**510(k) Number:**     K161336    

### Submitter's Name / Contact Person

#### **Manufacturer**

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

#### **Contact Person**

Adam Ettl  
Sr. Regulatory Product Specialist  
Tel: 763-656-4300  
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### General Information

<b>Trade Name</b>	VSI StraitSet micro-introducer kit
<b>Common / Usual Name</b>	Micro-introducer kit
<b>Classification Name</b>	21 CFR 870.1310; DRE; Vessel dilator for percutaneous catheterization
<b>Predicate Device</b>	K071330; GaltStick introducer system (Galt Medical Corp.)

### Device Description

The VSI StraitSet is a 6F x 20cm triaxial introducer comprised of a sheath (with hydrophilic or silicone coating), dilator and a stiffening cannula. The VSI StraitSet is packaged as a kit with the following components:

- (1) 0.018" x 60 cm guidewire
- (1) 21 G x 7 cm echogenic access needle or (1) 21 G 15 cm echogenic trocar needle with depth markings and locking stylet
- Optional: (1) 0.038" x 145 cm, 3 mm "J"/straight guidewire

### Indications for Use

The VSI StraitSet micro-introducer kit is intended for use in percutaneous introduction and placement of catheters and guidewires.

### Technological Characteristics Comparison

The VSI StraitSet micro-introducer kit and the predicate device have identical indication statements and are similar in design. The subject and predicate devices are both micro-introducer kits intended for introduction and placement of catheters and guidewires. The subject and predicate device are available in similar configurations which include: one hydrophilic or silicone

coated triaxial introducer, one 0.018” guidewire, one 21 G access needle and an optional 0.038” guidewire. The VSI StraitSet micro-introducer kit introducer, guidewire and access needle dimensions are the same as the predicate device.

### **Substantial Equivalence and Summary of Studies**

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

- Kink radius
- Fluoroscopy visualization
- Friction force
- Simulated use
- Peak tensile force
- Torque
- Liquid leak under pressure
- Aspiration
- Hydrophilic coating particulate
- Visual inspection
- Guidewire fracture
- Guidewire flex
- Depth mark durability
- Guidewire passage

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

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute System Toxicity
- Material Mediated Pyrogenicity
- ASTM Hemolysis (Complete)
- Complement Activation
- In-Vitro Hemocompatibility
- Coagulation
- Thrombogenicity

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