



Food and Drug Administration
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October 20, 2016

Vascular Solutions, Inc.
Ms. Beka Vite
Sr. Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K162272
Trade/Device Name: Fluent Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: MAV
Dated: September 28, 2016
Received: September 29, 2016

Dear Ms. Vite:

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,


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)

K162272

Device Name

Fluent inflation device

Indications for Use (Describe)

The Fluent inflation device is intended for use during cardiovascular procedures to create, maintain and monitor pressure in the balloon catheter.

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.

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2 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: August 11, 2016

510(k) Number: K162272

Submitter’s Name / Contact Person

Manufacturer

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

Contact Person

Beka Vite
Sr. Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-656-4253

General Information

Trade Name	Fluent inflation device
Common / Usual Name	Inflation device
Classification Name	21 CFR 870.1650, MAV – Syringe, balloon inflation
Predicate Device	K152387 – Fluent inflation device (Vascular Solutions, Inc.)

Device Description

The Fluent inflation device consists of a barrel with a plunger, locking button, rotating handle, manometer, and high pressure tube with a rotating luer lock. The manometer is graduated between vacuum and 30 atm.

Intended Use

The Fluent inflation device is intended for use during cardiovascular procedures to create, maintain and monitor pressure in the balloon catheter.

Technological Characteristics Comparison

The Fluent inflation device is similar in design and identical in intended use to the predicate device as they are both single-use, sterile inflation devices used to inflate, deflate, and measure the pressure in angioplasty balloon catheters. Both devices are manually operated by manipulation of a rotating handle, and both include a locking mechanism to maintain pressure or achieve rapid deflation.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence that the modified Fluent inflation device is substantially

equivalent to the predicate device. The modified Fluent inflation device is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The modified device design has been verified through the following tests:

- Pressure (hand pressurization, repeat hand pressurization, static pressure)
- Force (button lock and unlock)
- Plunger Torque
- Ease of Use

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