DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2015

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

Re: K152387
Trade/Device Name: Fluent Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II
Product Code: MAV
Dated: November 12, 2015
Received: November 16, 2015

Dear Beka 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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" (21CFR 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,

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

Indications for Use

510(k) Number (if known): K152387

Device Name: Fluent inflation device

Indications for Use: The Fluent inflation device is intended for use during cardiovascular procedures to create, maintain and monitor pressure in the balloon catheter. The sidearm extension tubing is intended to provide a sterile fluid pathway between two devices.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: August 20, 2015

510(k) Number: K152387

Submitter's Name / Contact Person

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

Contact Person
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Regulatory Product Specialist
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General Information

Trade Name	Fluent inflation device
Common / Usual Name	Inflation device
Classification Name	21 CFR 870.1650, MAV – Syringe, balloon inflation
Predicate Devices	K082755 – Sedat Flamingo (Sedat) K963749 – High Pressure Injection Lines (Maxxim Medical)

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 male luer lock. The manometer is graduated between vacuum and 30 atm. The extension tubing is a plastic tube with plastic luer lock connector hubs (one male and one female) at either end. It is available in 25 cm and 50 cm lengths.

Indications for Use

The Fluent inflation device is intended for use during cardiovascular procedures to create, maintain and monitor pressure in the balloon catheter. The sidearm extension tubing is intended to provide a sterile fluid pathway between two devices.

Technological Characteristics Comparison

The Fluent inflation device and the sidearm extension tubing are similar in design and intended use to their respective predicate devices. The Fluent and its predicate 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. The extension tubing and its predicate are both plastic tubes with plastic luer lock connector hubs (one male and one female) at either end.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and mechanical tests, and results did not raise new issues of safety or effectiveness. The Fluent inflation device and extension tubing are substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and indications for use. The Fluent inflation device design has been verified through the following tests:

- Ease of Use
- Pressure
- Force
- Plunger Torque
- Tensile
- Fluid Capacity
- Luer Compatibility

The extension tubing design has been verified through the following tests:

- Luer Compatibility
- Pressure

Fluent inflation device and extension tubing samples passed the following biocompatibility tests required by ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- ASTM Hemolysis
- Complement Activation
- Coagulation
- In Vitro Hemocompatibility
- Thrombogenicity (extension tubing only)

The results of the design verification tests met the specified acceptance criteria and did not raise new questions of safety and effectiveness. Therefore, the Fluent inflation device is substantially equivalent to the predicate devices.