K033721

FEB 1 3 2004

510(K) SUMMARY

Common/Usual Name: Fluid Administration Set

Product Trade Name: Auto Fill Syringe Kit

Classification Name: Fluid Administration kit for use in General and Plastic Surgery and in Dermatology
21 CFR 880.5440 (Product Code FPA)

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369

Establishment Registration: 2134812

Contact: Sara L. Coon
Senior Regulatory Affairs Associate
(763) 656-4300 phone
(763) 656-4250 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description: The Auto Fill Syringe Kit consists of a control syringe and fluid administration set with check valve.

Intended Use: The Auto-Fill™ Syringe Kit is indicated for the introduction of dilute lidocaine solutions into subcutaneous tissues for the purposes of tumescent local anesthesia.

Summary of Non-Clinical Testing: Testing has been conducted to verify the integrity and strength of the bond used to attach the check valve to the tubing.

Predicate Devices: The Disposable Coronary Control Syringe marketed by Merit Medical Systems, Inc.; the Merit Administration Set marketed by Merit Medical Systems, Inc.; the KMI Repetitive Injection kit marketed by KMI Kolster Methods, Inc.; fluid administration set, marketed by Merit Medical Systems, Inc..

Conclusions: The Auto-Fill Syringe Kit is substantially equivalent to the identified predicate devices based on a comparison of the indications for use and the components supplied and the technological characteristics of the supplied components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2004

Ms. Sara L. Coon
Senior Regulatory Affairs Specialist
Vascular Solutions
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K033721
Trade/Device Name: Vascular Solutions Auto-Fill™ Syringe Kit
Regulation Number: 880.5860, 880.5440
Regulation Name: Piston Syringe Intravascular Administration Set
Regulatory Class: II
Product Code: FMF, FPA
Dated: November 25, 2003
Received: November 26, 2003

Dear Ms. Coon:

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 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). 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/tray. 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.

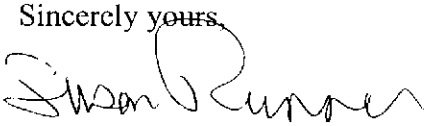
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Vascular Solutions Auto-Fill™ Syringe Kit

Indications For Use: The Auto-Fill™ Syringe Kit is indicated for the introduction of dilute lidocaine solutions into subcutaneous tissues for the purposes of tumescent local anesthesia.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033721