

K063851 (P.1 of 2)



JAN 26 2007

Vascular SOLUTIONS

510(k) Summary

510(k) Number: _____

Date Prepared

December 27, 2006

Submitter Information

Submitter's Name/
Address:

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

Establishment Registration 2134812

Contact Person:

Patrice Stromberg
Sr. Regulatory Affairs Associate
(763) 656-4243 telephone
(763) 656-4200 fax
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Device Information

Trade Name:
Classification Name:
Product Codes:
Regulations:

Auto-Fill® Syringe Kit
Piston Syringe; Intravascular Administration Set
FMF, FPA
Class II, 880.5860, 880.5440

Performance Standards

No performance standards applicable to this product have been developed under Section 514 of the Act.

K463851(P.2 of 2)

Predicate Device(s)

- Auto-Fill™ Syringe Kit marketed by Vascular Solutions, Inc. (K033721)
- IV Administration Set marketed by DeRoyal® (Codan USA) (pre-amendment device)
- Angiographic Control Syringe, marketed by DeRoyal, Inc. (CDI) (K920135)
- L.O.N. Pressure Monitoring Lines, CPC Lines, Administration, marketed by DeRoyal (CDI) (K853099)
- Multi-Ad Fluid Dispensing System, marketed by B. Braun Medical, K792227

Device Description

The Auto-Fill Syringe Kit contains disposable components that may be used to deliver dilute lidocaine solutions into subcutaneous tissues for the purposes of local anesthesia. The kit provides an extension tubing mechanism to conveniently refill a 12cc syringe from an IV bag eliminating the need for multiple reconnections to the solution container.

The kit contains the following items:

- 12cc Control Syringe
- IV tubing with spike, dual check valve, and roller clamp
- Extension line (various lengths ranging from 6” to 48”)

Intended Use/Indications for Use

The AutoFill® 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

Performance Testing: The static and dynamic pressure capabilities of the extension tubing for the Auto-Fill Syringe Kit were tested. The extension tubing met the specified design and performance requirements.

Biocompatibility Testing: The material in the components used to create the Auto-Fill Syringe Kit has been demonstrated to be biocompatible through biocompatibility testing performed by the original manufacturers.

Summary of Clinical Testing

No clinical evaluations of this product have been performed.

Statement of Equivalence

Through the data and information presented, Vascular Solutions considers the Auto-Fill® Syringe Kit to be substantially equivalent to the identified predicate devices based on a comparison of the indications for use 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

Ms. Patrice Stromberg
Senior Regulatory Affairs Associate
Vascular Solutions, Incorporated
6464 Sycamore Court North
Minneapolis, Minnesota 55369

JAN 26 2007

Re: K063851

Trade/Device Name: Auto-Fill Syringe Kit, Model 7600
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FPA
Dated: December 27, 2006
Received: December 28, 2006

Dear Ms. Stromberg:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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

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 our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.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 Statement

510(k) Number (if known): _____

Device Name: Auto-Fill® Syringe Kit

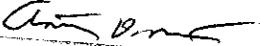
Indications for Use:

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 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K463857