K042487

JAN 21 2005

510(K) SUMMARY

Sponsor:	Avanca Medical Devices, Inc. 800 Bradbury SE Albuqerque, NM 87106
Submitted By:	Ferguson Medical Consultant to Avanca Medical Devices, Inc.
Contact Information:	Phone: 505.272.7000 FAX: 505.272.7000
Classification Name:	Piston syringe, antistick
Common/Usual Name:	Syringe, safety syringe, injection syringe, aspiration syringe and others
Proprietary Name:	Procedur-SF
Classification Number:	21 CFR 880.5860/Procode ~~90~~ 80 FMF/~~90~~ 80 MEG
Substantial Equivalence:	Becton Dickinson Single Use Hypodermic Syringes (K980987) and Retractable Technologies, Inc. VanishPoint Safety Syringe (K980069)
Device Description:	The Procedur-SF device is a piston safety syringe
Intended Use:	The Procedur-SF device is intended to be used to inject fluids into, or withdraw fluids from, the body, while reducing the risk of sharps injuries and potential for syringe reuse
Technological Characteristics:	The Procedur-SF device utilizes two syringes assembled in a plastic holder. The syringe plungers are connected by a pulley

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2005

Avanca Medical Devices, Incorporated
C/O Mr. Frank Ferguson
Official Correspondent
Ferguson Medical
12200 Academy Road, NE #931
Albuquerque, New Mexico 87111

Re: K042487
Trade/Device Name: Procedur SF Safety Syringe Device
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 12, 2004
Received: December 27, 2004

Dear Mr. Ferguson:

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.

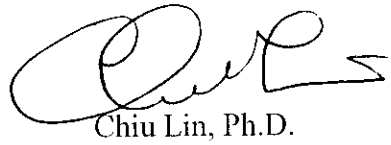
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean 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 (301) 443-6597 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

510(k) Number (If known): K042487

Device Name: Procedur-SF

Indications For Use:

The Procedur-SF device is used to inject fluids into, or withdraw fluids from, the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) And/Or Over-The- Counter Use _____ (21 CFR 807 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

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