K032417

DEC 2 3 2003

"510k Summary"

Preparation Date: July 20, 2003

Submitter: AM2PAT, Inc.
9400 Ransdell Road, Suite 10
Raleigh, NC 27603
Phone: (919) 552-9689
Fax: (919) 552-7400

Contact: Dushyant Patel, President

Device Name: Heparin Lock Flush Syringe

Device Common/Usual Name: Heparin Lock Flush Solution, USP

Device Classification Name: Catheter, Intravascular, Therapeutic, Short Term Less Than 30 Days

Product Code: NGT – Device, Flush, Vascular Access

Substantially Equivalent Devices:

Company	*Product/Device*	*510k Number*
EMT-Rx	Saline IV Flush Syringe	K002142
Becton Dickinson	BD PosiFlush™ Heparin Lock Flush Syringe	K011967
Baxter Healthcare	Heparin Lock Flush Syringe	K003245
Medefil, Inc	Heparin IV Flush Syringe	K020996

Device Description:

The proposed device is a sterile, single use, standard piston type syringe that is available in various fill volumes and syringe sizes containing either 10 or 100 USP u/ml (units) Heparin Lock Flush Solution for Injection.

The syringe uses a sterile, polypropylene luer lock fitting or blunt tip cannula. The piston syringe consists of a polypropylene barrel with a luer lock adapter assembled with a polypropylene plunger and a polyisoprene seal. The dispensing end of the syringe is covered with a tip cap closure.

Intended Use:

The AM2PAT Heparin Lock Flush Syringe and its predicate products are intended for prescription use to flush compatible intravenous administration sets and indwelling intravascular access devices.

K032417

Comparison to legally marketed devices:

The technological characteristics of the new device to legally marketed predicate devices are the same in that:

All devices have the same intended use
All devices are pre-filled with a heparin lock flush solution, USP
All are single use disposable products
All are sterile and pryogen free
All are manufactured using an aseptic process
All are available in similar syringe sizes and fill volumes
All use a polypropylene piston-type syringe
All are packaged in a wrapper or polybag and sealed
All use manual energy

Non-Clinical Testing:

The physical properties of the materials used to manufacture the Heparin Lock Flush Pre-Filled Syringe are tested by suppliers to ensure they meet either USP Class VI plastic test requirements or ISO 10993 Part 1 for all fluid path components. Materials that come into contact with the body have been tested and found to be safe and effective for their intended use. This information was submitted as part of 510 K002142 for the EMT-Rx Saline Flush Syringe. These materials are widely used in similar, and other medical devices and have been cleared through FDA.

Test data have been generated for stability and container/closure suitability. Performance testing indicates that the proposed device meets all functional requirements and supports its suitability for use.

Conclusion:

The Heparin Lock Flush Pre-Filled Syringe is substantially equivalent to the predicate devices cited with respect to indications for use, device design, materials, and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

Mr. Dushyant Patel
President
AM2Pat, Incorporated
9400 Ransdell Road
Raleigh, North Carolina 27603

Re: K032417
Trade/Device Name: Heparin Lock Flush Syringe – 10 and 100 units/mL
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 17, 2003
Received: December 18, 2003

Dear Mr. Patel:

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.

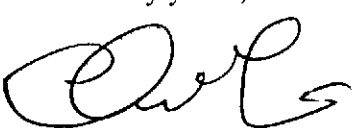
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/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

K032417

Indications for Use

Applicant: AM2PAT

510(k) Number (if known): N/A K032417

Device Name: Heparin Flush Syringe – 10 and 100 units/mL

Indications for Use: Lock

Lock

The Heparin Flush Syringe, 10 and 100 units/mL is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

Susanna F. Barnard

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

510(k) Number: K032417

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21CFR 801.109)