K061497

p.1 of 3

510(k) SUMMARY
Excelsior Medical Heparin Lock Flush Syringes
(1 Unit per ml and 2 Units per ml)

FEB 23 2007

This 510(k) summary is provided as part of the Premarket Notification for Excelsior Medical Heparin Lock Flush Syringes (1Unit/ml and 2 Units/ml)

Submitter: **Excelsior Medical**
1933 Heck Ave.
Neptune, New Jersey 07753
Phone: +1-732-776-6079
Facsimile: +1-732776-7600

Contact Person: John J. Talarico

Date Prepared: February 21, 2007

Name of Device: Excelsior Medical Heparin Lock Flush Syringes (1Unit/ml and 2 Units/ml)

Common or Usual Name: Heparin Lock Flush Syringe

Classification Name: Intravascular Catheter 21 CFR 880.5200

Predicate Devices:
Medefil 1 U/ml Flush Syringe
Hospital filled 1 U/ml Flush Syringe

Intended Use / Indications for Use

A. **Intended Use**

The Excelsior Medical Heparin Lock Flush Syringes are intended for use in flushing IV catheters and IV tubing.

B. **Indications for Use**

To maintain patency of vascular access devices designed for intermittent or infusion therapy. Prior to and after administration of intermittent medication, entirely flush the vascular access device with Heparin Lock Flush Solution, USP. Use in accordance with any warnings or precautions appropriate to medication being administered. This device is not to be used for anticoagulant therapy.

C. Contraindications

- Heparin Lock Flush Solution, USP should not be used in patients with thrombocytopenia or with an uncontrollable active bleeding state. Heparin Lock Flush Solution USP for IV flush should not be used for anticoagulant therapy. Heparin Lock Flush Solution USP is not for use in patients with documented hypersensitivity to heparin or pork products.

Technological Characteristics

Excelsior Medical Heparin Lock Flush Syringes are polypropylene latex-free syringes which contains a labeled volume of a sterile, non-pyrogenic solution of Heparin Lock Flush Solution, USP derived from porcine intestinal mucosa in 0.9 sodium chloride USP with a pH range of 5.0 – 7.5.

Heparin is a heterogenous group of straight-chain anionic mucopolysaccharides, called glycosminoglycans, having anticoagulant properties. Although others may be present, the main sugars occurring in heparin are: (1)α-L-iduronic acid 2 – sulfate, (2)2-deoxy-2sulfamino-α-D-glucose, 6 –sulfate, (3)ß-D-glucuronic acid, (4)2-acetamido-2-deoxy- α-D-glucose, and (5) α –L-iduronic acid. These sugars are present in decreasing amounts, usually in the order (2)>(1)>(4)>(3)>(5),are joined by glycosidic linkages, forming polymers of varying sizes. Heparin is strongly acidic because of its content of covalently linked sulfate and carboxylic acid groups. In heparin sodium, the acidic protons of the sulfate units are partially replaced by sodium ions.

The Excelsior Medical Heparin Lock Flush is designed to be injected into a vascular access device. The appropriate concentration of Heparin Lock Flush Solution USP should be based on current practice standards and institutional policies and procedures.

Performance Data

The Excelsior Medical Heparin Lock Flush Syringes are tested according to the specifications documented in Design Verification Testing Reports and independent laboratory testing. In all instances, the Excelsior Medical Heparin Lock Flush Syringes functioned as intended and met all pass criteria as expected.

Substantial Equivalence

The Excelsior Medical Heparin Lock Flush Syringes are as safe and effective as the Medefil's 1 U/ml Flush Syringe and Hospital pharmacy filled 1 U/ml Flush Syringes. The Excelsior Medical Heparin Lock Flush Syringes have the same

intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Excelsior Medical Heparin Lock Flush Syringes and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrates that the Excelsior Medical Heparin Lock Flush Syringes are as safe and effective as the Medefil's 1 U/ml Flush Syringe and Hospital pharmacy filled 1 U/ml Flush Syringe. Thus, the Excelsior Medical Heparin Lock Flush Syringes are substantially equivalent to the predicate devices in construction, materials, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John J. Talarico
Vice President & Regulatory Affairs
Excelsior Medical Corporation
1933 Heck Avenue
Neptune, New Jersey 07753

FEB 23 2007

Re: K061497
Trade/Device Name: Excelsior Medical Heparin Lock Flush Syringes (1Unit/ml and 2 Units/ml)
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NZW
Dated: December 15, 2006
Received: January 31, 2007

Dear Mr. Talarico:

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 Statement

510(k) Number (if known): K061497

Device Name: Excelsior Medical Heparin Lock Flush Syringes (1Unit/ml and 2 Units/ml)

Indications For Use: Excelsior Medical Heparin Lock Flush Syringes (1Unit/ml and 2 Units/ml) are indicated for use in maintaining patency of vascular access devices designed for intermittent or infusion therapy. Prior to and after administration of intermittent medication, entirely flush the vascular access device with Heparin Lock Flush Solution, USP. Use in accordance with any warnings or precautions appropriate to medication being administered. This device is not to be used for anticoagulant therapy

Prescription Use __X__ AND/OR (Part 21 CFR 801 Subpart D) 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)

[illegible] of Anesthesiology, General Hospital,
[illegible] Control, Dental Devices

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