DEC 1 8 2008

510(k) Summary of Safety and Effectiveness

Manufacturer Name:	Excelsior Medical Corporation
Contact Name:	John Linfante
Title:	VP, Regulatory & Quality Assurance
Postal Address:	1933 Heck Avenue Neptune, NJ 07753
Phone Number:	732-776-7525
Fax:	732-776-7600
Date:	November 19, 2008

Device Proprietary Name:	Sterile Field Saline Flush Syringe
Device Common or Usual Name:	Saline Flush Syringe
Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term, Less Than 30 Days
Classification Code	NGT
Classification Panel	Infection Control
Regulation Number	880.5200

Predicate Device:

Substantial equivalence is claimed to the following devices:

- Excelsior Medical Heparin Lock Flush Syringe (1 U/mL and 2 U/mL)
- Excelsior Sterile Field Saline Flush Syringe (K053120)

Description of the Device

The Excelsior Medical Saline pre-filled Syringe(s) in Sterile Field Packaging will contain 10ml of 0.9% sodium chloride solution, USP in a 10 ml syringe. This device will be marketed as one or two syringes packaged in a sterile pouch.

Each syringe will contain a white tip cap and associated label with a clear background. In addition, the syringe label will contain a lot number, expiration date and graduation marking.

Each filled and labeled syringe will be packaged in a pouch which is a two part envelope that contains printed information on one side and is clear on the other side.

Intended Use of the Device

The Saline pre-filled Syringe(s) in Sterile Field Packaging is intended for use in flushing IV catheters and IV tubing

Performance

Design Verification is based on the Stability Study. The results of these tests demonstrate that the Excelsior Medical Saline Syringe(s) in a Sterile Field Packaging performed in an equivalent manner to the predicate device and is safe and effective when used as intended.

Substantial Equivalence

The Sterile Field Saline Flush Syringes are similar to the predicate devices in terms of solution, sterilization, shelf-life and labeling.

Conclusion

Based on the information provided in this 510(k) premarket notification, the Excelsior Medical Sterile Field Saline pre-filled Flush Syringe is substantially equivalent in terms of safety and effectiveness to the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2008

Mr. John Linfante
Vice President, Regulatory Affairs and Quality Assurance
Excelsior Medical Corporation
1933 Heck Avenue
Neptune, New Jersey 07753

Re: K082837
Trade/Device Name: Excelsior Saline Pre-Filled Syringe(s) In Sterile Field Packaging
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: November 19, 2008
Received: November 20, 2008

Dear Mr. Linfante:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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:

Device Name: Excelsior Saline pre-filled Syringe(s) in Sterile Field Packaging

Indication for Use: Excelsior Sterile Field Saline Flush Syringe(s) are intended for use in flushing IV catheters and IV tubing.

The product is provided as:

- One 10mL syringe containing 10mL of 0.9% saline solution
- Two 10mL syringes each containing 10mL of 0.9% saline solution

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 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
Office of Device Evaluation

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

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510(k) Number: K082837