

DEC 9 2005

K053120

## 510(k) SUMMARY

### Submitted by:

Ruben Martinez  
Director, Regulatory/Quality  
Excelsior Medical Corporation  
1923 Heck Avenue  
Neptune, NJ 97753

### Proposed Device:

Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes

### Predicate Device:

Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes

### Device Description and Statement of Intended Use:

The modification which is the subject of this Special 510(k) is substitution of the current dust cover packaging with Sterile Field packaging. All other aspects of the product design remain unchanged.

Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes are intended for flushing IV catheters and IV tubing. This is the same intended use previously cleared for the currently marketed Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes.

### Summary of Technological Characteristics of New Device to Predicate Device

The technological characteristics of Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes do not differ from the currently marketed Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes. The devices use the same fundamental scientific technology and have the same intended use.

### Discussion of Non-Clinical Tests; Conclusions Drawn from Nonclinical Tests

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 9 2005

Mr. Ruben Martinez  
Director Regulatory/Quality  
Excelsior Medical Corporation  
1923 Heck Avenue  
Neptune, New Jersey 07753

Re: K053120  
Trade/Device Name: Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes  
Regulation Number: 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: II  
Product Code: FOZ  
Dated: November 28, 2005  
Received: November 30, 2005

Dear Mr. Martinez:

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

**Indications for Use Statement**

510(k) Number (if known): K053120

Device Name: Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes

Indications For Use:

Excelsior Sterile Field Saline Flush Syringes and Heparin Lock Flush Syringes are indicated for use in flushing IV catheters and IV tubing.

*John H. Murphy MD 12/2/05*  
Anesthesiology, General Hospital,  
Device Control, Dental Devices  
Number K 053120

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (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)