FEB 10 2011

510(k) Summary

Manufacture Name:	Excelsior Medical Corporation
Contact Name:	John Linfante
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Title:	VP, Regulatory Affairs and Quality Assurance
Date:	February 4, 2011

Device Proprietary Name:	SwabFlush™
Device Common or Usual Name:	Flush Syringe with Device Disinfectant Cap
Classification Name:	Saline Vascular Access Flush
Classification Code:	NGT/LKB
Regulation Number:	General Hospital

Predicate Devices:
Substantial equivalence is claimed to the following devices as related to intended use, technology and design characteristics:

- Excelsior Disposable Syringe w/ Normal Saline (0.9% Sodium Chloride), K962938 (Excelsior Medical Corporation)
- Excelsior Saline pre-filled Syringe(s) in Sterile Field Packaging, K082837 (Excelsior Medical Corporation)
- SwabCap®, K083508 (Excelsior Medical Corporation)

Description of the Device
SwabFlush™ is a saline intravenous flush syringe that is combined with an integrated SwabCap®.

Each SwabFlush™ syringe contains a sterile, non-pyrogenic isotonic solution of 0.9% Sodium Chloride Injection USP, 9 mg NaCl per ml, with an osmolarity of 0.31mOsm/mL, pH 4.5 – 7.0.

A SwabCap® is a luer access valve cap that contains 70% isopropyl alcohol as a disinfectant. A SwabCap® is designed to securely fit on swab-able luer access valves. The product is intended for single-use and is provided sterile.

The SwabFlush™ provides the healthcare professional with immediate access to the SwabCap® luer access valve disinfectant cap after an IV flush.

Intended Use/Indications for Use
The flush syringe is intended for flushing IV catheters and IV tubing. The integrated SwabCap® is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between the line accesses. SwabCap® will disinfect the valve five (5) minutes after application and act as a physical barrier to contamination for up to ninety-six (96) hours under normal conditions if not removed.

Technological Characteristics
The SwabFlush™ syringe has the same technological characteristics as the predicates. SwabFlush™ syringe and predicate syringes are all single use, disposable prefilled saline syringes.

The SwabFlush™ syringe is similar in design and uses the same types of materials as the Excelsior Medical Disposable Syringe with Normal Saline (K962938) and Saline pre-filled Syringe(s) in Sterile Field Packaging (K082837). The SwabFlush™ syringe, like the predicate syringes, has a standard male luer lock fitting which is intended to connect to standard female luer lock fittings, including luer access valves. The saline contained in the SwabFlush™ syringe and predicate syringes meet the same requirements for 0.9% Sodium Chloride Injection, USP. Both the SwabFlush™ syringe and predicate syringes meet the same requirements for syringe functional characteristics such as, but not limited to, injection force and liquid/air leakage. The SwabFlush™ syringe is filled, sterilized, and packaged using the same equipment and processes of the Disposable Syringe with Normal Saline (K962938). The SwabFlush™ syringe and the Disposable Syringe with Normal Saline (K962938) are intended for the same user and indicated for the same use.

The integrated SwabCap® within the SwabFlush™ syringe is identical to the predicate device. There have been no changes to the intended use, design, materials or processing of SwabCap® as cleared under K083508.

Technological Modifications
The SwabFlush™ has two unique technological modifications from the predicate devices. The first is a modification of the thumb press end of the plunger. Instead of a flat surface, the end has an open cup feature that allows a single fully assembled and packaged SwabCap® to be integrated with the syringe. The second modification is in the form of rounded recesses molded into the opening of the syringe barrel. This feature prevents a fully injected syringe plunger from rotating. This anti-rotational feature allows the fully injected syringe to become a tool for SwabCap® application and facilitates its installation to the luer access device.

Substantial Equivalence Discussion
The subject device is similar to the predicate devices based on intended use, technology and design. No changes have been made to the design of the SwabCap® as cleared by the FDA for integration into the syringe plunger.

Non Clinical Testing Data to Demonstrate Safety

All of the non clinical testing was conducted in accordance to the requirements of design control. The following is a summary of the non clinical data that demonstrate the SwabFlush™ syringe is safe and effective. It consists of the following:

DESIGN VERIFICATION

Excelsior has demonstrated that the SwabFlush™ syringe meets all ISO 7886-1: Sterile Hypodermic Syringes for single use standards and ISO 594-1&-2: Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment.

The device was confirmed to meet all biocompatibility requirements of ISO 10993: Biological evaluation of medical devices.

Sterilization validations were performed to validate the effectiveness of the sterilization methods to achieve the desired sterility assurance level.

Additional tests performed ensure the SwabFlush™ syringe functions to hold and apply a SwabCap®, while not affecting the disinfectant content of the SwabCap®. The saline flush was verified to comply with 0.9% Sodium Chloride Injection USP monograph requirements. The verification also included the controlled aging of SwabFlush™ to verify all product requirements including sterility throughout the shelf life. Ship testing was performed on a representative final packaged product for drop, vibration, and compression as specified by applicable ISTA or ASTM standards.

All results met the criteria established in the testing.

DESIGN VALIDATION

A Design Validation was done to verify that the SwabFlush™ meets the clinical need expected for a typical flush procedure in a simulated clinical setting.

Conclusion

Based on the information provided in this 510(k) premarket notification, SwabFlush™ 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

FEB 10 2011

Re: K101270
Trade/Device Name: SwabFlush™
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: January 25, 2011
Received: January 27, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

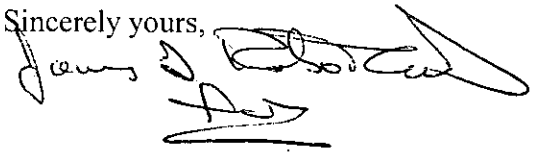
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Canter for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K101270

Device Name: SwabFlush™

Indication for Use: The flush syringe is intended for flushing of IV catheters and IV tubing.

SwabCap® is intended for use on a swab-able luer access valve as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between the line accesses. SwabCap® will disinfect the valve five (5) minutes after application and act as a physical barrier to contamination for up to ninety-six (96) hours under normal conditions if not removed.

The SwabFlush™ product is provided as:

1. 10 ml fill in 10 ml saline flush syringe with integrated SwabCap®.
2. 5 ml fill in 10 ml saline flush syringe with integrated SwabCap®.
3. 3 ml fill in 10 ml saline flush syringe with integrated SwabCap®.

Prescription Use ___X___ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (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
Anesthesiology, General Hospital, Infection Control and Dental Devices

510(k) _____

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

510(k) Number: K101270