Excelsior Medical Corp.
Roshana Ahmed
Manager
c/o CanReg, Incorporated
4 Innovation Drive
Dundas, On, L2H 7P3
Canada

March 11, 2022

Re: K083508
Trade/Device Name: Swabcap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Roshana Ahmed:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 28, 2009 and the correction letter dated March 6, 2019. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 6, 2019

Excelsior Medical Corp.
Roshana Ahmed
Manager
4 Innovation Drive
Dundas, Ontario, L2H 7P3
Canada

Re: K083508
Trade/Device Name: SwabCap™
Regulatory Class: Unclassified
Product Code: QBP
Dated: November 24, 2008
Received: November 26, 2008

Dear Roshana Ahmed:

This letter corrects our substantially equivalent letter of April 28, 2009.

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 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083508

Indications for Use

510(k) Number: K083508

Device Name: SwabCap™

Indication for Use: 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 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.

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
Office of Device Evaluation

for 510(k)_____

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

510(k) Number: K083508

510(k) Summary of Safety and Effectiveness

Manufacture Name:	Excelsior Medical Corporation
Contact Name:	John Linfante
Title	VP Regulatory and Quality Assurance
Postal Address:	1933 Heck Avenue Neptune, NJ 07753
Phone Number:	732-643-6088
Fax:	732-776-7600
Date:	February 12, 2009
Device Proprietary Names:	SwabCap™
Device Common or Usual Name:	Alcohol pad
Classification Name:	Pad, Alcohol, Device Disinfectant
Classification Code	LKB
Classification Panel	General Hospital
Regulation Number	N/A

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

- Effectiv™ Cap, Hospira, Inc., K080579
- Curos™ Port Protector, Ivera Medical, K080466
- Alcohol Prep Pad, Professional Disposables Inc. 510(k) Number: Unknown

Description of the Device
The SwabCap™ is designed to securely fit on swab-able luer access valves. The cap contains 70% isopropyl alcohol. The product is intended for single-use and is provided sterile, latex free, preservative free and DEHP free.

Intended Use of the Device
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 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.

Substantial Equivalence
The SwabCap™ is similar to the predicate devices based on the intended use, design, technology, antimicrobial agent and performance.

Conclusion
Based on the information provided in this 510(k) premarket notification, the SwabCap™ is substantially equivalent in terms of safety and effectiveness to the predicate devices identified above.

K083508
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Section J - Substantial Equivalence

Table J-1 compares the SwabCap™ to the predicate devices.

Table J-1: Comparison to Predicates for SwabCap™

510(k) Number	K083508	K080579	K080466	Unknown
Device Name	SwabCap™	Effectiv™ Cap	Curos™ Port Protector	Alcohol Prep Pad
Manufacturer	Excelsior Medical Corp.	Hospira, Inc.	Ivera Medical Corporation	Professional Disposables Inc.
Intended Use	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 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 Effectiv™ Cap is a device containing 70% IPA. When left in place for 5 to 10 minutes the cap decontaminates the injection port; thereafter the cap provides a physical barrier during intended use. For use with standard needleless ports.	The Curos™ Port Protector is a device containing 70% Isopropyl alcohol. When left in place for 5 to 15 minutes the Curos™ Port Protector decontaminates the injection port; thereafter the Curos™ Port Protector provides a physical barrier during the intended use.	For topical cleansing prior to injections or venipuncture. Each soft pad is saturated with 70% isopropyl alcohol. For professional and hospital use.
Additional Claims	DEHP, Latex and Preservative Free	DEHP and Latex Free	unknown	unknown
Antimicrobial Agent	70% Isopropyl Alcohol	70% Isopropyl Alcohol	70% Isopropyl Alcohol	70% Isopropyl Alcohol
Sterilization	Gamma Irradiated	Unknown	Non-sterile	Gamma irradiated
Packaging	Individually wrapped with peel off foil lid.	Individually wrapped with peel off foil lid.	Individually wrapped.	Individually packaged in packets.

Discussion:

The SwabCap™ device is similar to the predicate devices in terms of intended use, design and material characteristics.

Conclusion:

It is concluded that the SwabCap™ device is substantially equivalent to the predicate devices.