Excelsior Medical Corp.
John Linfante
1933 Heck Ave
Neptune, NJ 07753

March 31, 2022

Re: K130975
Trade/Device Name: Swabcap And Swabflush
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear John Linfante:

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 December 24, 2013 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

FDA U.S. FOOD & DRUG ADMINISTRATION

March 6, 2019

Excelsior Medical Corp.
John Linfante
1933 Heck Ave
Neptune, NJ 07753

Re: K130975
Trade/Device Name: SwabCap® and SwabFlush®
Regulatory Class: Unclassified
Product Code: QBP
Dated: April 8, 2013
Received: April 8, 2013

Dear John Linfante:

This letter corrects our substantially equivalent letter of December 24, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially 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

Indications for Use

510(k) Number: K130975

Device Name: SwabFlush® (3 mL saline in 10 mL syringe, 5 mL saline in 10 mL syringe, and 10 mL saline in 10 mL syringe)

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

SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.

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)

Sreekanth Gutala -S

Division Sign-Off
Office of Device Evaluation

510(k) K130975

Indications for Use

510(k) Number: K130975

Device Name: SwabCap®

Indication for Use: SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.

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)

Sreekanth Gutala -S

Division Sign-Off
Office of Device Evaluation

510(k) K130975

510(k) Summary

DEC 2 4 2013

Manufacturer Name:	Excelsior Medical Corporation
Address:	1933 Heck Avenue Neptune, NJ 07753
Contact Name:	John Linfante
Title:	VP Regulatory and Quality Assurance
Phone Number:	732-643-6088
Fax Number:	732-776-7600
Date Prepared:	November 1, 2013

Device Proprietary Name:	SwabCap®
Device Common or Usual Name:	Device Disinfectant Cap
Classification Name:	Pad, Alcohol, Device Disinfectant
Classification Code:	LKB
Regulation Number:	N/A
Device Classification	Unclassified

Predicate Devices:

Substantial equivalence is claimed to the following device as related to intended use, design, and material characteristics:

- SwabCap®, Excelsior Medical Corporation, K083508

Description of the Device

SwabCap® is a plastic threaded cap that houses a small sponge saturated with 70% isopropyl alcohol. The device is designed to securely fit on swab-able luer access valves to disinfect the valve surface and maintain antiseptic conditions between line accesses. SwabCap® is a sterile, single-use device, provided as a stand-alone product.

Intended Use/Indications for Use

SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.

The purpose of this 510(k) is to extend the indications for use to include surface disinfection for up to 7 days.

Summary of Technological Characteristics

The subject SwabCap® has similar technological characteristics as the predicate device in terms of design, chemical composition, and materials of construction.

Both devices are designed with a standard luer thread to fit on swab-able luer access valves. There have been no changes to the product dimensions, antimicrobial agent, and sterilization processes.

Slight modifications of the cap and colorant resin materials, as well as the foil lid cover were made to improve manufacturing efficiency or due to product availability. All changes were made within the same generic material families and were implemented under design controls.

Comparison of Substantial Equivalence

The Substantial Equivalence table below compares the intended use and key technological and design characteristics of the subject and predicate devices. A discussion of the similarities and differences in technological characteristics is provided above.

510(k) Number	**SwabCap® K130975**	**SwabCap® K083508**
Intended Use	SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.	The 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.
Design	Same	Designed with standard luer thread to fit on swab-able luer access valves.
Materials	• Holder – same	• Holder – Alathon M6580

510(k) Number	SwabCap® K130975	SwabCap® K083508
	• Cap – same • Sponge – same • Colorant – Pantone 151C	• Cap – Medical grade Santoprene • Sponge – SUGI absorbent material • Colorant – Pantone 151C
Antimicrobial Agent	Same	70% Isopropyl Alcohol
Dimensions	Same	Diameter 20 mm Height 13.5 mm
Sterility	Same	Gamma irradiated

Non-Clinical Testing

Non-clinical testing including biocompatibility studies, sterilization validation, and antimicrobial testing were undertaken to support the changes to the product and its intended use.

Conclusion

The data provided within the 510(k) submission support that the product is as safe and as effective as the predicate device, and therefore, is substantially equivalent to the identified predicate device.