ICU Medical
Nichelle Cato
Sr. Regulatory Affairs Associate
600 N. Field Drive
Lake Forest, Illinois 60045

March 11, 2022

Re: K190918
Trade/Device Name: SwabTip Male Disinfectant Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Nichelle Cato:

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 March 6, 2020. 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, 2020

ICU Medical
Nichelle Cato
Sr. Regulatory Affairs Associate
600 N. Field Drive
Lake Forest, Illinois 60045

Re: K190918
Trade/Device Name: SwabTip Male Disinfectant Cap
Regulatory Class: Unclassified
Product Code: QBP
Dated: February 4, 2020
Received: February 5, 2020

Dear Nichelle Cato:

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

for Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190918

Device Name

SwabTip™ Male Disinfectant Cap

Indications for Use *(Describe)*

SwabTip™ is intended for use on ISO male luer connectors as a cover to protect the luer from potential contamination. The SwabTip™ acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabTip™ will disinfect the male luer (30) seconds after application and maintains a disinfected luer surface for up to four days (96 hours) if not removed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K190918 - 510(k) Summary

Submitter Information	
Name	ICU Medical
Address	600 North Field Drive Lake Forest, IL. 60046
Phone number	(224)-706-2852
Fax number	N/A
Establishment Registration Number	3013319212
Name of contact person	Nichelle Cato, Manager, Global Regluatory Affairs
Date prepared	3/5/2020
Name of device	
Trade or proprietary name	SwabTip™ Male Disinfectant Cap
Common or usual name	Cap, Device Disinfectant
Classification	Unclassified
Unclassification Reason	Pre-Amendment
Panel	General Hospital
Product Code(s)	QBP
Legally marketed device(s) to which equivalence is claimed	SwabCap® – K130975
Reason for 510(k) submission	New SwabTip™ to be used on male luers.
Device description	SwabTip™ Male Disinfectant Cap is an accessory to the terminal male luer of an intravenous administration set that is used to disinfect and maintain a physical barrier when the administration set is not in use. The SwabTip™ is a cap that when attached to an ISO compatible male luer slip, lock, or spin luer, delivers a small volume of 70% isopropyl alcohol to the external surfaces of the male luer including the internal threads. SwabTip™ is a single use sterile fluid path cap, provided in multi-unit delivery strip.
Intended Use of Device/Indication for use	SwabTip™ is intended for use on ISO male luer connectors as a cover to protect the luer from potential contamination. The SwabTip™ acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabTip™ will disinfect the male luer (30) seconds after application and maintains a disinfected luer surface for up to four days (96 hours) if not removed.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate (K130975)**	**Comparison**
Device Name	SwabTip™	SwabCap®	
Common Name	Cap, Device Disinfectant	Cap, Device Disinfectant	Same
Indications for Use	SwabTip™ is intended for use on ISO male luer connectors as a cover to protect the luer from potential contamination. The SwabTip™ acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabTip™ will disinfect the male luer (30) seconds after application and maintains a disinfected luer surface for up to four days (96 hours) if not removed.	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. SwabCaps®' 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.	Antimicrobial Efficacy and Microbial Barrier testing were performed on the subject device for differences in disinfection time and maintaining a disinfected luer surface.
Design	SwabTip™ is used on a male luer	SwabCap® is used with a luer valve	Luer compatibility testing was conducted on subject device. Subject device is for male luers, the predicate is for a luer valve.
Materials of Construction	Outer Cap/Holder (packaging and cap) - High-Density Polyethylene	Outer Cap Holder (packaging) – Alathon M6580 Cap – Medical Grade Santoprene	Subject device was tested according to ISO 10993-1

	Sponge – Polyester Urethane foam	Sponge – SUGI absorbent material	Subject device was tested according to ISO 10993-1
	Foil - Polyethylene Terephthalate & Low-Density Polyethylene	Foil - Polyethylene Terephthalate & Low-Density Polyethylene	Same
Antimicrobial Agent	Isopropyl Alcohol (70%)	Isopropyl Alcohol (70%)	Same
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
Shelf Life	2 years	2 years	Same
Sterilization Method	Radiation (sterile fluid path)	Radiation	Same
SAL	10^{-6}	10^{-6}	Same

Discussion:

There are three major differences between the predicate and subject indications for use:

- The predicate SwabCap® disinfects a valve and the subject device SwabTip™ disinfects a male luer
- There is a decreased exposure time from the predicate to the subject which is, 5 minutes to 30 seconds disinfection time for male luer
- There is a decrease in time, from which the disinfectant cap can be left in place, providing a physical barrier. The predicate disinfectant cap can be left on for 7 days and the subject disinfectant cap can be left on for 96 hours (4 days).

Summary of Technological Characteristics:

The subject device SwabTip™ has the same Indications for Use and is also technologically equivalent to the predicate device SwabCap®. They use similar functional specifications, materials and design (with minor modifications). They have the same sterilization method and shelf life. A comparison between the subject device – SwabTip™ and its predicate was performed to support a substantial equivalence determination. Apart from the above mentioned modifications, there are no technological differences between the subject and the predicate device. These modifications were assessed through antimicrobial efficacy testing, microbial barrier performance testing, and Luer compatibility testing. The conclusion of the comparison analysis is that the subject device – SwabTip™ is substantially equivalent to the currently marketed predicate device – SwabCap®.

Summary of Non-Clinical Testing

Non-clinical verification of SwabTip™ has been conducted to evaluate the performance and functionality of the device. The results of these tests have demonstrated that the subject device meets the performance requirements and ultimately supports a substantial equivalence determination of SwabTip™ to the predicate device SwabCap®. A summary of the testing conducted is presented below.

Performance Data

The following performance data were provided in support of the substantial equivalence to internal test methods or standard:

- Antimicrobial (Disinfectant) Efficacy Testing
- Microbial Barrier Performance Test
- Male Luer Compatibility Testing
- Visual Inspection
- Foil Functional Test
- Lid Peel Force
- Integrity by Weight
- Seal Leak Testing of Holder and Foil Lid
- IPA Ingress/Alcohol Fluid Path Testing
- Pyrogenicity Testing

Particulates

Particulate contamination testing was performed by following USP <788> to demonstrate particulate levels on the SwabTip™ device meet USP <788> requirements.

Efficacy Study

A time kill study was conducted to determine how rapidly and effectively SwabTip™ kills a variety of microorganisms. SwabTip™ was tested for antimicrobial activity against six selected organisms using an industry standard protocol for time-kill assays. The results demonstrated that SwabTip™ produces a 4 Log_{10} reduction are summarized below in Table 1.

Table 1. Efficacy Test Results

Challenge Strain	Acceptance Criteria	Observed	Result
P. aeruginosa (ATCC #9027)	≥4.0 on 10/10 Samples	10/10	Pass
S. aureus (ATCC #6538)	≥4.0 on 10/10 Samples	10/10	Pass
E. coli (ATCC #11229)	≥4.0 on 10/10 Samples	10/10	Pass
S. epidermidis (ATCC #14990)	≥4.0 on 10/10 Samples	10/10	Pass
C. albicans (ATCC #10231)	≥4.0 on 10/10 Samples	10/10	Pass
C. glabrata (ATCC #2001)	≥4.0 on 10/10 Samples	10/10	Pass

Biocompatibility Testing

Biocompatibility testing for SwabTip™ was conducted in accordance with ISO 10993-1 and FDA's June, 2016 Guidance titled, "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process,'" as recognized by FDA. Testing included:

- ISO Elution Cytotoxicity per ISO 10993-5
- Guinea Pig Maximization Sensitization per ISO 10993-10
- Rabbit Intracutaneous Reactivity (Irritation) per ISO 10993-10
- Acute Systemic Injection in Mice per ISO 10993-11
- Hemolysis - Direct Contact and Extract Methods per ISO 10993-4
- Rabbit Pyrogen Test per 10993-11
- Subacute/Subchronic Study per ISO 10993-11

Conclusion

The SwabTip™ meets the functional claims and intended use as described in the product labeling. The functional specifications, components, design, sterilization, shelf-life and materials of construction of SwabTip™ are substantially equivalent to the predicate device. Test results from the performance testing conducted demonstrate that SwabTip™ met all acceptance criteria requirements. Therefore, the subject device – SwabTip™ is substantially equivalent to the currently marketed predicate device – SwabCap®. The changes outlined above, do not raise new or different questions of safety or effectiveness.