March 27, 2026

ICU Medical Inc.
Nichelle Cato
Sr. Regulatory Affairs Manager
951 Calle Amanecer
San Clemente, California 92673

Re: K252006
Trade/Device Name: OTTO™ Disinfecting Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP
Dated: February 25, 2026
Received: February 25, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252006

Device Name
OTTO™ Disinfecting Cap

Indications for Use *(Describe)*
OTTO is intended for use on swabbable needlefree connectors as a cover to protect the needlefree connectors from potential contamination. OTTO acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access.

OTTO will disinfect the connector thirty (30) seconds after application and maintains a disinfected connector surface for up to seven (7) days 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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K252006 - 510(k) Summary

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92 for OTTO™ Disinfecting Cap.

Submitter Information	
Name	ICU Medical
Address	600 North Field Drive Lake Forest, IL. 60045
Phone number	779-378-7029
Fax number	N/A
Establishment Registration Number	3013319212
Name of contact person	Nichelle Cato, Sr. Global Regulatory Affairs Manager
Date prepared	March 27, 2026
Name of Device	
Trade or proprietary name	OTTO™ Disinfecting Cap
Common or usual name	Cap, Device Disinfectant
Classification	Class 2
Regulation Number	21 CFR 880.5440
Regulation Name	Intravascular Administration Set
Review Panel	General Hospital
Product Code(s)	QBP
Predicate Device (Legally marketed device(s) to which equivalence is claimed)	
Trade or proprietary name	SwabCap™ (K130975)
Common or usual name	Cap, Device Disinfectant
Classification	Class 2
Regulation Number	21 CFR 880.5440
Regulation Name	Intravascular Administration Set
Review Panel	General Hospital
Product Code(s)	QBP
Reason for 510(k) submission	To reduce the disinfectant time from 5 minutes to 30 seconds.
Device description	The OTTO™ Disinfecting Cap is a sterile disposable cap designed to disinfect swabbable needlefree female connectors with 70% isopropyl alcohol (IPA) when attached to an intravenous (IV) catheter. The OTTO™ product line complements the ICU Medical Clave family of needlefree connectors; however, it is designed to work with other on-market swabbable needlefree female

	connectors used in peripheral intravenous catheters, indwelling central venous or arterial access catheters.
Intended Use/ Indication for Use	OTTO is intended for use on swabbable needlefree connectors as a cover to protect the needlefree connectors from potential contamination. OTTO acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. OTTO will disinfect the connector thirty (30) seconds after application and maintains a disinfected connector surface for up to seven (7) days if not removed.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	***Subject* OTTO™ Disinfecting Cap**	***Predicate* SwabCap 510(k) K130975**	**Comparison**
Product Code	QBP	QBP	Same
Common Name	Cap, Device Disinfectant	Cap, Device Disinfectant	Same
Intended Use	OTTO™ is intended for use on swabbable needlefree connectors as a cover to protect the needlefree connectors from potential contamination. OTTO™ acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. OTTO™ will disinfect the connector thirty (30) seconds after application and maintains a disinfected connector surface for up to seven (7) days 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 serves as a disinfecting cleaner for use prior to line access.	Same
Indications for Use Statement	OTTO™ is intended for use on swabbable needlefree connectors as a cover to protect the needlefree connectors from potential contamination. OTTO™ acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. OTTO™ will disinfect the connector thirty (30) seconds after application and maintains a disinfected connector surface for up to seven (7) days 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 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.	Similar Disinfection time reduced from 5 mins to 30 seconds. The subject device microbial inactivation demonstrates a higher level of effectiveness in the reduction of microorganisms.
Technology			
Design	Outer Cap Holder (packaging) – Designed for Foil Strip	Outer Cap Holder (packaging) – Designed for Single Foil Lid	Similar The subject device is sealed on a strip while the predicate is individually sealed.

Characteristic	*Subject* OTTO™ Disinfecting Cap	*Predicate* SwabCap 510(k) K130975	Comparison
	Cap	Cap	Same
	Sponge	Sponge	Same
	Isopropyl Solution	Isopropyl Solution	Same
	Foil – Muti Seal Configuration on Foil Strip	Foil – Single Foil Lid Seal	Different The subject device is sealed on a strip that can be placed on an IV pole, while the predicate is individually sealed. The change allows for each cap to be removed on an IV pole.
Materials	Outer Cap Holder (packaging) – HDPE	Outer Cap Holder (packaging) – HDPE	Same
	Cap – Santoprene (Pink)	Cap – Santoprene (Orange)	Similar Base cap material is the same while the colorant is different. Subject device was tested according to ISO 10993-1
	Sponge - Polyurethane based foam	Sponge - Compressed Cellulose foam	Different Subject device was tested according to ISO 10993-1
	Isopropyl Solution (IPA)	Isopropyl Solution (IPA)	Same
	Foil	Foil	Same
User Population	Home and Hospital Use	Home and Hospital Use	Same
Performance	Designed to perform as a disinfectant cap to disinfect needlefree Luer connectors	Designed to perform as a disinfectant cap to disinfect needlefree Luer connectors	Same
Antimicrobial Agent	70% Isopropyl Alcohol (IPA)	70% Isopropyl Alcohol (IPA)	Same
Disinfecting Time	Min: 30 Seconds, Max: 7 days	Min: 5 minutes, Max: 7 days	Different

Characteristic	*Subject* OTTO™ Disinfecting Cap	*Predicate* SwabCap 510(k) K130975	Comparison
			Reduction in minimum disinfecting time was confirmed through efficacy testing
Compatibility	ISO 80369-7 needlefree Luer connectors	ISO 80369-7 needlefree Luer connectors	Same
Biocompatibility	Meets the applicable material test requirements for ISO 10993.	Meets the applicable material test requirements for ISO 10993.	Same
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
Sterilization Method	Radiation	Radiation	Same
Sterility Assurance Level	Sterility Assurance Level is 10^{-6}	Sterility Assurance Level is 10^{-6}	Same
Single Use	Yes	Yes	Same
Shelf Life	1 year	2 years	Different

There are 3 major and 2 minor differences between predicate and subject features. The main feature enhancements made to the subject OTTO™ Disinfecting Cap in comparison to the predicate device (K130975) are the following:

Major differences

- Disinfection time reduced from 5 minutes to 30 seconds
  - Reduction in disinfecting time was assessed through antimicrobial efficacy testing and does not affect the performance of OTTO. The disinfectant cap demonstrates effective microbial ingress prevention, achieving a ≥4 $\log_{10}$ reduction throughout the claimed shelf life and does not raise new questions of safety and effectiveness.
- Sponge material
  - Subject Device - Polyurethane based foam
  - Predicate Device - Compressed Cellulose foam

    The sponge differences have been tested in performance, microbiological, biocompatibility and particulate testing that support safe use and effectiveness and therefore, does not raise new questions of safety and effectiveness.
- Cap changes
  - Subject device cap color is pink, and the predicate cap is orange – both devices use the same based Santoprene material. The difference is the colorant.
    - The cap colorant has been tested in performance and biocompatibility testing that support safe use and effectiveness and therefore, does not raise new questions of safety and effectiveness.

Minor differences

- The subject device includes five (5) caps sealed on a strip that can be hung on an IV pole, while the predicate is individually sealed caps.
- Shelf-life expiration date 2 years (predicate) and 1 year (subject)

Summary of Technological Characteristics:

OTTO™ Disinfecting Cap has a similar Indications for Use and is also technologically equivalent to the predicate SwabCap™. They use the same functional specifications, materials and design (with minor modifications). They have the same sterilization method and different shelf life. A comparison between the subject device and its predicate was performed to support a substantial equivalence determination. The substantial equivalence comparison included the device's indications for use, design, technological characteristics, materials, sterilization and shelf life. The conclusion of the comparison analysis is that the subject device – OTTO™ is substantially equivalent to the currently marketed predicate SwabCap™.

Summary of Non-Clinical Testing

Non-clinical verification of OTTO™ Disinfecting Cap has been conducted to evaluate the safety, performance and functionality. The results of these tests have demonstrated the overall safety of the subject device and ultimately supports a substantial equivalence determination of OTTO™ to the predicate device SwabCap™. A summary of the testing conducted is presented below.

Performance Data

The following performance data was provided in support of the claimed shelf life and the substantial equivalence to internal test methods or standard(s):

- Visual Inspections
- Needle-Free Connector Compatibility Testing
- Cap Performance Testing
- Antimicrobial (Disinfectant) Efficacy Testing
- Microbial Barrier Performance Test
- Sterile Barrier and Packaging Evaluation
    - Distribution & Handling Evaluation
    - Seal Leak Testing
    - Lid Peel Force Evaluation
    - IPA Ingress Testing
- Resistance to separation from unscrewing Resistance to Axial Load
- Alcohol volume
- Torque On/Off / Override Force
- Air and Liquid Leakage
- Stress Cracking

Particulates

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

Clinical Information

Clinical data was not needed to support a substantial equivalence determination.

Efficacy Study

The efficacy of OTTO was tested to demonstrate that it can disinfect the connector thirty (30) seconds after application and maintains a disinfected connector surface for up to seven (7) days if not removed. The disinfectant cap demonstrates effective microbial ingress prevention, achieving a ≥4 $\log_{10}$ reduction across two gram-negative (*E. coli*, *P. aeruginosa*), two gram-positive (*S. aureus*, *S. epidermidis*), and two fungal (*C. albicans*, *C. glabrata*) challenge organisms using worst-case simulated-use test articles.

Microbial Barrier Study

ICU Medical provided non-clinical performance test data in order to demonstrate the cap maintains a physical barrier to contamination to the luer access device for 7 days. The disinfectant cap subject device demonstrated effective microbial barrier properties for luer access devices when subjected to aerosolized microbial fallout using challenge organism *Bacillus atrophaeus*.

Biocompatibility Testing

Biocompatibility testing for OTTO™ Disinfecting Cap was conducted in accordance with ISO 10993-1 and FDA's 2023 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. OTTO was evaluated as an Externally Communicating device with Indirect Blood Path contact for a Prolonged (> 24 hours to ≤ 30 days) duration.

Conclusion

The OTTO™ Disinfecting Cap 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 OTTO™ is substantially equivalent to the predicate device. Test results from the performance testing conducted demonstrate that OTTO™ met all acceptance criteria requirements. Therefore, the subject device – OTTO™ 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.