



February 11, 2026

1World Vista Medical
% Laurie Lewandowski
Consultant, Regulatory and Quality
Honkanen Consulting, Inc.
738 Saddle Wood Dr.
Eagan, Minnesota 55123

Re: K251592

Trade/Device Name: SteriHub™ Disinfecting Device and Protective Cover
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: QBP
Dated: January 12, 2026
Received: January 12, 2026

Dear Laurie Lewandowski:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 WOLLOSCHICK -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251592

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Please provide the device trade name(s).

?

SteriHub™ Disinfecting Device and Protective Cover

Please provide your Indications for Use below.

?

The SteriHub™ Disinfecting Device and Protective Cover is intended for active disinfection of needleless connectors.

The SteriHub Disinfecting Device and Protective Cover provides a physical barrier to contamination for up to 7 days, if not removed. The SteriHub may be used in the home or healthcare facility.

Please select the types of uses (select one or both, as applicable).

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

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K251592 - 510(k) SUMMARY

1. SUBMITTER INFORMATION

Submitter:

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Date Prepared:

February 11, 2026

2. DEVICE INFORMATION

Proprietary Name: **SteriHub™ Disinfecting Device and Protective Cover**
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Common/Usual Name: Device Disinfectant Cap
Regulatory Class: Class II
Product Code: QBP

3. PREDICATE DEVICE INFORMATION

Proprietary Name: PureHub Disinfecting Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Common/Usual Name: Device Disinfectant Cap
Regulatory Class: Class II
Product Code: QBP
510K Number: K193190

4. REFERENCE DEVICE INFORMATION

Proprietary Name: Site-Scrub IPA Device
 Regulation Number: Unclassified / pre-amendment
 Common/Usual Name: Pad, Alcohol, Device Disinfectant
 Regulatory Class: Class II
 Product Code: LKB
 510K Number: K112791

5. DEVICE DESCRIPTION

The SteriHub™ Disinfecting Device and Protective Cover (SteriHub) is a single use disinfecting tool to be used on needleless connectors. The SteriHub, Model Number is SH-001, sterile cap contains 70% Isopropyl Alcohol (IPA) and disinfects the needleless connector via an active mechanical friction (scrub) while applying IPA. The SteriHub device also functions as a protective cover against contamination and recontamination of needleless connectors for up to 7 days.

The device consists of HDPE housing that contains an element and core that are filled with 70% IPA. The device is sealed with a foil lid. Disinfection takes place by screwing the SteriHub onto connector, scrubbing by twisting back and forth ten (10) times, like juicing an orange. The combination of scrubbing and IPA application provides an active disinfection.

6. INDICATIONS FOR USE

The SteriHub™ Disinfecting Device and Protective Cover is intended for active disinfection of needleless connectors.

The SteriHub Disinfecting Device and Protective Cover provides a physical barrier to contamination for up to 7 days, if not removed. The SteriHub may be used in the home or healthcare facility.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Attribute / Device Characteristic	SteriHub Disinfecting Device and Cover (Subject Device)	PureHub Disinfecting™ Cap (K193190) Predicate
Intended Use	To disinfect needleless connectors prior to access and to act as a physical barrier for up to 7 days if not removed.	Identical
Indications for Use	The SteriHub™ Disinfecting Device and Protective Cover is intended for active disinfection of needleless connector. The SteriHub Disinfecting Device and Protective Cover provides a physical barrier to contamination for up to 7 days, if not removed. The SteriHub may be used in the home or healthcare facility.	BD PureHub™ Disinfecting Caps are intended to be used as a disinfecting cleaner for swabbable needle-free luer connectors prior to access and to act as a physical barrier between line accesses. BD PureHub™ Disinfecting Cap will disinfect the needle-free luer connector one (1) minute after application and act as a physical barrier for up to seven (7) days, if not removed.

Attribute / Device Characteristic	SteriHub Disinfecting Device and Cover (Subject Device)	PureHub Disinfecting™ Cap (K193190) Predicate
User Population	Healthcare providers and home users trained by health care providers	General Use
Use Conditions	Home and health care facility	Identical
Use	Needleless connectors	Identical
Target Population	Patients that require devices with needleless connectors	Identical
Principle of Operation	Active (physical) scrub disinfection with 70% IPA of needleless connectors. The SteriHub fits the needleless connector maintaining a disinfecting barrier for up to 7 days.	Passive, soak, 70% IPA disinfection The PureHub fits the needleless connector maintaining a disinfecting barrier for up to 7 days.
Components	<ul style="list-style-type: none"> • Ribbed Housing - HDPE • Element -Thermoplastic • Core - LDPE • 70% IPA solution • Foil Lid 	<ul style="list-style-type: none"> • Ribbed Housing - HDPE • Sponge – Polyester Urethane • 70% IPA solution • Foil lid
Disinfectant Active Ingredient	70% Isopropyl Alcohol	Identical
Disinfecting Protocol*	10 twists back and forth Active disinfection	Immediate - 1 minute dwell time Passive disinfection
Physical Barrier	After disinfecting, leave on up to 7 days	Identical
Features	Element and core are designed to scrub the septum, rim, and threads of needleless connectors with 70% IPA.	Element designed to soak the needleless connectors with 70% IPA.
Sterility	Gamma Irradiation	Identical
SAL	1×10^{-6}	Identical
Target Organisms	<ul style="list-style-type: none"> • Candida albicans, • Candida glabrata, • Escherichia coli, • Pseudomonas aeruginosa, • Staphylococcus aureus (MRSA), • Staphylococcus epidermidis (MRSE) 	<ul style="list-style-type: none"> • Candida albicans, • Candida glabrata, • Escherichia coli, • Pseudomonas aeruginosa, • Staphylococcus aureus (MRSA), • Staphylococcus epidermidis (MRSE) • Acinetobacter baumannii

* The SteriHub Disinfecting Device and Protective Cover provides an active disinfecting protocol like the reference device, Site Scrub (K112791) - twist back and forth a minimum of 10 seconds, dry 5 seconds.

The following summarizes why the identified differences in technological characteristics between the subject and predicate devices do not raise new questions of safety and effectiveness

- **Indications for Use Wording Differences:**
Both devices disinfect needleless connectors using 70% IPA and provide a barrier for up to 7 days. Wording differences clarify use environment and disinfection description but do not change intended use, function, or risk profile and therefore do not raise new questions of safety and effectiveness.
- **User Population Description:**
The subject device specifies healthcare providers and trained home users, which is consistent with the predicate terminology of general use and supported by usability validation. This does not change risk and does not raise new questions of safety and effectiveness.
- **Principle of Operation — Active Scrub vs Passive Dwell:**
Both devices use 70% IPA to disinfect connectors; the subject uses mechanical scrubbing while the predicate uses dwell time. IPA scrub disinfection is an established approach and performance testing confirms effectiveness, so this difference does not raise new questions of safety and effectiveness.
- **Disinfecting Protocol — Twisting Action vs Dwell:**
The subject device requires a labeled twisting step that was supported by performance and microbiological testing and is consistent with legally marketed scrub-based disinfecting devices. This difference in user interaction does not change intended function and does not raise new questions of safety and effectiveness.
- **Internal Element and Material Design — Thermoplastic/LDPE vs Sponge:**
The subject device uses a molded element/core rather than a sponge to deliver 70% IPA and provide mechanical friction during disinfection. The design difference has been tested in performance, microbiological, biocompatibility and particulate testing that support safe use and effective disinfection and therefore, does not raise new questions of safety and effectiveness.
- **Scrub Feature vs Soak Feature:**
Mechanical scrubbing versus soaking represents an alternate IPA delivery method to the same connector surfaces, with verified performance results. This does not raise new questions of safety and effectiveness.
- **Target Organism Panel Differences:**
The organism tested substantially overlap, with the subject device being tested against the most common organisms representing clinically relevant species. Testing demonstrates effective disinfection. The target panel differences do not alter mechanism or intended use and do not raise new questions of safety and effectiveness.

8. DISCUSSION

The intended use of the subject and predicate device are the same; both disinfect a needleless connector using 70% IPA and act as a physical barrier for up to 7 days. The disinfecting method in the subject device consists of scrubbing with 70% IPA while the predicate uses a disinfecting one-minute dwell with 70% IPA. The reference device, SiteScrub K112791, disinfects by scrubbing with 70% IPA similar to the subject device.

The differences in technological characteristics do not raise different questions of safety and effectiveness, and performance testing demonstrates that the subject device performs as intended and is as safe and effective as the predicate devices.

9. NON-CLINICAL TESTING

The following tests were performed on the SteriHub Disinfecting Device and Protective Cover at T=0 and T=6 months.

In Vitro Antimicrobial Efficacy (immediate disinfection and post 7 days)

- *Candida albicans*,

- Candida glabrata,
- Escherichia coli,
- Pseudomonas aeruginosa,
- Staphylococcus aureus (MRSA),
- Staphylococcus epidermidis (MRSE)

Test results showed >4 log count reduction in all scenarios.

Testing at T=0 and T=aged

- | | |
|--|---------------------------------|
| • Resistance to separation from unscrewing | • Resistance to Axial Load |
| • Physical Attributes | • Visual – Device and Packaging |
| ○ Alcohol volume | |
| ○ Component fit (housing /element, element/core) | |
| ○ Dimensions | |
| • Torque On/Off Force | • Particulate Testing (USP 788) |
| • Override | • Package Integrity |
| • Air and Liquid Leakage | • Usability Testing |
| • Stress Cracking | |

Alcohol Ingress testing was conducted and demonstrated that across three different needless connector types and at two different temperatures, 20-25°C and 37°C, alcohol ingress into the connector was less 14 mmole / L.

Biocompatibility Testing was performed

- Cytotoxicity: MEM Extraction (ISO 10993-5, 2009)
- Hemolysis: Direct and Indirect (ISO 10993-4 2017)
- Sensitization: Guinea Pig Maximization Test (ISO10993- 10)
- Irritation: Intracutaneous Reactivity Test (ISO10993-23, 2021)
- Acute Systemic Toxicity (ISO 10993-11, 2017)
- Subacute Toxicity (ISO 10993-11, 2017)
- Material Mediated Pyrogenicity (ISO10993- 11, 2017)
- LAL Endotoxin USP <85>

All devices met all acceptance criteria.

10. CONCLUSION

The 1WorldVista Medical SteriHub Disinfecting Devices and Protective Covers are substantially equivalent in terms of the indications for use, technological characteristic, performance testing and comparison to the cited predicate, and do not present any new questions of safety and effectiveness.