April 5, 2024

Cleansite Medical, Inc.
Neal Hartman
VP, Regulatory Affairs/Quality Assurance
125 Highway 101
Solana Beach, California 92075

Re: K223914
Trade/Device Name: ACTIV™ Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: QBP
Dated: April 1, 2024
Received: April 2, 2024

Dear Neal Hartman:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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, 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)*
K223914

Device Name
ACTIV™ Cap

Indications for Use *(Describe)*
ACTIV Cap is intended for use on a needleless vascular access port as an active cleaning and disinfecting device prior to IV access and to act as a passive, protective barrier for up to 7 days if not removed. ACTIV Cap disinfects needleless vascular access ports in one (1) minute after application and achieves at least a >5-log reduction as tested in vitro against 6 organisms - Staphylococcus aureus, Staphylococcus epidermis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans.

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.

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K223914 - 510(K) SUMMARY

Submitter Information

Company Name:	Cleansite Medical, Inc.
Company Address:	125 Highway 101 Solana Beach, CA 92075
Company Phone:	858.735.7090
Primary Contact:	Neal Hartman Director, Regulatory Affairs/Quality Assurance nealenhartman@gmail.com
Secondary Contact:	Dan Chambers CEO dan@cleansitemed.com
Date:	April 2, 2024

Device Identification

Device Trade Name:	ACTIV™ Cap
Common Name:	Device Disinfectant Cap
Classification Name(s):	Intravascular administration set
Regulation(s):	21 CFR 880.5440
Device Class:	2
Product Code(s):	QBP
Review Panel:	General Hospital

Identification of Predicate Devices

The Subject Device is substantially equivalent to the following legally marketed, predicate device:

Device Name	Classification Name/Regulation	Product Code	510(K) Number	Clearance Date
Curos Port Protector	Cap, Device Disinfectant/ Unclassified	QBP	K111992	1/12/2012

Device Description

The Subject Device is a sterile, single-use device that is used to clean and disinfect needleless vascular access ports and then act as a cover for the access port between uses. Covering between uses maintains the port's cleanliness. The Subject Device is made of a plastic inner threaded housing snapped into an outer cap and incorporates a foam substrate that protrudes into the central bore of the inner housing and is moistened with the active disinfectant, 70% Isopropyl Alcohol (IPA). The IPA-filled cap is sealed with a poly/foil film to prevent excessive loss of the active ingredient and maintain the sterile barrier.

The Subject Device reduces the risk of unintentional removal by requiring a slight compression force (i.e., pinching) on the cap's side to remove, which force causes the outer housing to engage the inner housing so as to allow the inner and outer housings to be rotated in unison in order to attach and remove the Subject Device from a threaded needleless vascular access port. Without compression, once secured to a needleless vascular access port the Subject Device's outer housing can be rotated in relation to the inner housing and needleless vascular access port to further clean the surface of the access port.

Once the Subject Device is installed on a needless vascular access port, the device passively disinfects the contacting surfaces with the 70% IPA moistened foam.

Ten (10) sealed devices are assembled onto a card hanger that can be hung in an IV pole. Twenty (20) assembled cards are packaged into an inner carton. The instructions for use are printed on the outside on the inner carton. Twenty-four (24) inner cartons are packaged into a corrugated shipper. The packaging shipper is sterilized by gamma irradiation to a Sterility Assurance Level (SAL) of 10-6.

Indications for Use

ACTIV Cap is intended for use on a needleless vascular access port as an active cleaning and disinfecting device prior to IV access and to act as a passive, protective barrier for up to 7 days if not removed. ACTIV Cap disinfects needleless vascular access ports in one (1) minute after application and achieves at least a >5-log reduction as tested in vitro against 6 organisms - *Staphylococcus aureus, Staphylococcus epidermis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata*, and *Candida albicans*.

Comparison of Technological Characteristics with Predicate Device

Comparison Feature	Subject Device	Predicate Device	Comparison
Device name	ACTIV™ Cap	Curos Port Protector	
Manufacturer	CleanSite Medical, Inc.	Ivera Medical (3M)	

Comparison Feature	Subject Device	Predicate Device	Comparison
Indications for Use	ACTIV Cap is intended for use on a needleless vascular access port as an active cleaning and disinfecting device prior to IV access and to act as a passive, protective barrier for up to 7 days if not removed. ACTIV Cap disinfects needleless vascular access ports in one (1) minute after application and achieves at least a >5-log reduction as tested in vitro against 6 organisms - Staphylococcus aureus, Staphylococcus epidermis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans.	The Curos 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. Curos will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of Curos Protectors were tested in vitro against *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli and Pseudomonas aeruginosa, Candida glabrata, Candida albicans* and was found to have >4 log reduction. The Curos Port Protector may be used in the home or healthcare facility.	The Subject Device's microbial inactivation results demonstrate higher levels of effectiveness in the reduction of microorganisms than the Predicate with contact to the disinfectant only.
Connection Site	Needleless Access Ports	Needleless Access Ports	No Difference
Cap Materials	Molded Cap: HDPE/EVA Molded Insert: HDPE Foam: Polyurethane	Molded Cap: HDPE Molded Insert: HDPE Foam: Polyurethane	The Subject Device is a blend of two (2) materials for the molded cap versus the Predicate. Biocompatibility evaluations were conducted that demonstrate the biological safety of the Subject Device.
Disinfectant – Active Ingredient	70% Isopropyl Alcohol	70% Isopropyl Alcohol	No Difference
Minimum Disinfectant Time	One (1) Minute	Three (3) Minutes	The Subject Device's microbial inactivation results demonstrate the indicated minimum disinfectant time meets the acceptance criteria. The shorter disinfection time does not affect the safety or effectiveness of the Subject Device compared to the Predicate.
Maximum Disinfectant Time	Seven (7) Days	Seven (7) Days	No Difference
Disinfectant Delivery	IPA Reservoir (via foam sponge compression)	IPA Reservoir (via foam sponge compression	No Difference
Cap Length	0.54 inches	0.36 Inches	Minor increase in length. Does not impact intended use.
Cap Diameter	0.61 inches	0.54 inches	Minor increase in diameter. Does not impact intended use.

Comparison Feature	Subject Device	Predicate Device	Comparison
Requires compression (Squeezing) during installation/ removal?	Yes	No	The Subject Device has a cleaning feature that also reduces the risk of unintended device removal by requiring compression force (i.e., pinching) on the cap's side to attach and remove the Subject Device from a needleless vascular access port. Without compression, a user can rotate the cap's outer housing independently of its inner housing and the access port to which it is attached. The requirement to compress the Subject Device versus the predicate adds additional level of safety/efficacy from unintentional detachment from the needleless access port, where contamination to the access site could occur or choke hazard from ingesting the disinfecting cap that is a specific concern with pediatrics. If the Subject Device is not able to be removed from needleless access port, it could delay treatment at that access site. Usability studies were conducted that demonstrated users can adequately remove the Subject Device from needleless access ports.
Provided Sterile	Yes	Yes	No Difference
Single Use Device	Yes	Yes	No Difference
Plastic Housing to remain in place	Yes	Yes	No Difference
User Population	Hospital Use	Home and Hospital Use	Use environment was limited to healthcare facilities. Efficacy and performance are not impacted.
Shelf-Life	6-Months	2-Years	Currently, the Predicate has a longer demonstrated shelf-life. The shelf-life of the Subject Device will be increased when successful stability testing is completed. Safety and efficacy will be confirmed during subsequent stability assessments.

Summary of Testing Performed

Assessments were performed that include the following:

Test Interval	Evaluation	Performance Standard	Results
T=0	Biocompatibility – Externally Communicating Medical Device, Indirect Blood Path - Cytotoxicity - Sensitization - Intracutaneous Reactivity - Material Medicated Pyrogen - Systemic toxicity - Hemocompatibility - Leachables/Extractables	ISO 10933-1 (FDA No. 2-258)	Acceptable - Not considered to have a cytotoxic effect. - Did not elicit sensitization reactions. - No irritation was observed. - Non-pyrogenic - No acute systemic toxicity was observed. - Non-hemolytic - The organic/inorganic constituents detected in the Subject Device do not pose significant systemic risks to the patient.
T=0	Sterilization Validation (Gamma, VD_{max}^{25})	ISO-11137-2 (FDA No. 14-409)	Acceptable - SAL 10^{-6} - Bioburden: 21-35 CFUs - Product Sterility: No positives
T=0	Transportation Challenger	ASTM D4169 (FDA No. 14-499) ASTM D4322 (FDA No. 5-99).	Acceptable - No Damage to the device or its sterile barrier.
T=0	Endotoxin	ANSI/AAMI ST72 (FDA No. 14-541)	Acceptable - <0.0215 EU/device
T=0	Particulates	USP <788>	Acceptable - Met all acceptance criteria with regard to subvisible particulates greater than 10 microns
T=0	Torque to Needleless Access Port	N/A	Reference Only - Comparable to predicate device
T=0	IPA Ingress	N/A	Acceptable - The results show that the average IPA dosages were below the 14 mmol/L (“mM”) “critical concentration” calculated for neonatal patients in the Sauron article
T=0 T=6 Months	Packaging Integrity - Visual Inspection - Bubble Emission - Seal Peel Strength	ASTM F1886/F1886M (FDA No. 14-501) ASTM F2096 (FDA No. 14-482) ASTM F88/F88M (FDA No. 14-482_	Acceptable - No visual defects observed. - No air leak at test pressure - Seal strength >1.0 lbs..

Test Interval	Evaluation	Performance Standard	Results
T=0 T=6 Months	Functionality/Needleless Connector Displacement	N/A	Acceptable - None of the devices installed on each needleless valve type were observed with a leak when submerge in water.
T=0 T=6 Months	Resistance to Separation from Axial Load	ISO 80369-7 (FDA No. 5-133)	Acceptable - None of the devices separated below the minimum specification of 7.86 lb.
T=0 T=6 Months	Microbial Inactivation - Evaluated against the following microorganism: S. aureus, S. epidermidis, E. coli, P. aeruginosa, C. albicans, and C. glabrata	N/A	Acceptable - At 1-minute and 7-day contact exposure minimum of 5 log reduction achieved at a 99.9% confidence level.

Results of the evaluations demonstrate that the Subject Device meets the safety and performance requirements as it relates to its indication for use.

Conclusions Drawn from Nonclinical Evaluation

The results of the evaluation demonstrate that the Subject Device is substantially equivalent to the Predicate as it pertains to the indications for use and device performance.