April 20, 2020

Star Mountain Medical, Inc.
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Ave.
Crofton, Maryland 21114

Re: K192382
Trade/Device Name: CapKlenZ
Regulatory Class: Unclassified
Product Code: QBP
Dated: March 17, 2020
Received: March 23, 2020

Dear E.J. Smith:

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,

for Tina Kiang, Ph.D.
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)*
K192382

Device Name
CapKlenZ

Indications for Use *(Describe)*
When left in place for 3 minutes, the CapKlenZ disinfects needleless luer access valves; thereafter the CapKlenZ provide a physical barrier to contamination up to 168 hours under normal conditions 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.

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510(k) Summary

K192382

1 – Company Information & Contact Person

Company Name:	Star Mountain Medical, Inc.
Company Address:	9005 Montana Ave. Ste. A El Paso, Texas 79925
Telephone:	(915) 774-4321
Fax:	(915) 774-4323
Contact Person:	Cesar Rios, Quality Assurance & Regulatory Manager
Date Prepared:	08/23/2019

2 – Device Name & Classification

Trade/Device Name:	CapKlenZ
Common Name:	Device Disinfectant Cap
Regulation Number:	Unclassified
Classification Product Code:	QBP
Regulatory Class:	Unclassified

3 – Predicate Device

Legally Marketed Substantially Equivalent Predicate Device

Proprietary Name:	DualCap Solo™
Company Name:	Catheter Connections, Inc.
Common Name:	Device Disinfectant Cap
Regulation Number:	Unclassified
Classification Product Code:	QBP
Regulatory Class:	Unclassified
510(k) Number	K123065

4 – Device Description

CapKlenZ consists of a solid reservoir made of polyethylene, which contains an absorbent material and 70% isopropyl alcohol (70% IPA).
The opening of the reservoir is mechanically attached to a threaded membrane made of non-DEHP, non-latex elastomer, which lays in the internal geometry of the reservoir, this membrane is intended to be threaded to a needleless port connector and adapt to its shape. The reservoir and its contents are sealed with an extrusion laminated composite of polyester, polyethylene, aluminum foil, and a peelable sealant, which has to be removed before use.

Once the needleless port connector is threaded, the shape and elasticity of the threaded membrane, isolates the proximal end of the needleless port connector within the interior of the reservoir along with the absorbent material and 70% IPA. When the needleless port connector is threaded into the membrane, the circular movement of the connector scrubs its tip against the absorbent material and exposes it to 70% IPA in order to disinfect it.

The following table lists the model and size available for CapKlenZ.

Table 5.4 CapKlenZ Model and Size

Trade Name	Commercial Model Number	Diameter	Height	Antimicrobial agent	Color
CapKlenZ	CK-MPF10-200	17.1 mm (0.67 inch)	11.2 mm (0.44 inch)	70% Isopropyl Alcohol	Blue

5 – Intended Use

The CapKlenZ is designed to fit securely on needleless connectors. The reservoir contains 70% isopropyl alcohol, which disinfects the needleless port connector. It also contains a threaded membrane which acts as a barrier to prevent contamination of the needleless port connector.

6 – Indications for Use

When left in place for 3 minutes, CapKlenZ disinfects needleless luer access valves; thereafter the CapKlenZ provide a physical barrier to contamination up to 168 hours under normal conditions if not removed.

The Indications for use statement for CapKlenZ is not identical to the predicate device; however, the differences do not alter the intended use of the subject device nor do they raise new or different questions of safety and effectiveness. Both the subject device and predicate device have the same intended use.

Table 5.6 Indications for Use Comparison Table

Predicate Device IFU statement	Subject Device IFU statement
When left in place for five (5) minutes DualCap Solo™ disinfects needleless luer access valves; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.	When left in place for 3 minutes CapKlenZ disinfects needleless luer access valves; thereafter the CapKlenZ provides a physical barrier to contamination up to 168 hours under normal conditions if not removed.

The major differences in the predicate IFU and the subject device IFU are:

a) There is a decreased minimum exposure time, going from 5 minutes to 3 minutes disinfection time for luer access valves using CapKlenZ.

b) There is an increase in time going from 96 hours to 168 hours, in which the CapKlenZ can be left in place, providing a physical barrier.

In order to support the change in disinfection time indicated in the Indications for Use of CapKlenZ, *In-vitro* antimicrobial efficacy and microbial barrier studies were completed on CapKlenZ to support three (3) minutes and 168 hours disinfection time.

7 – Summary of Technological Characteristics Comparison

Based on a comparison of the indications for use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging, it is determined that the CapKlenZ is substantially equivalent to the predicate device. Table 5.7 below provides a comparison of the CapKlenZ and the predicate.

Table 5.7 Comparison of the CapKlenZ and the Predicate Device

Technical Characteristics / Principle of Operation	CapKlenZ Subject device	DualCap Solo™ 510(k) number K123065 Predicate device	Discussion
Diameter	17.1 mm (0.67 inch) ± 0.2 mm (0.007 inch)	11.0 mm (0.43 inch)	The difference in dimension between the predicate device and the subject device was evaluated per ISO 594-2, Dimensional, physical and functional attributes test.
Height	11.2 mm (0.44 inch) ± 0.2 mm (0.007 inch)	20.9 mm (0.82 inch)	The difference in dimension between the predicate device and the subject device was evaluated per ISO 594-2, Dimensional, physical and functional attributes test.
Reservoir Material	Polyethylene	Polypropylene	The difference in material between the predicate device and the subject device was evaluated per ISO 10993-1.
Internal Membrane	Non-DEHP, non-latex elastomer	Not Applicable	The difference in material and design characteristic between the predicate device and the subject device was evaluated per ISO 594-2, Dimensional, physical and functional attributes test, and ISO 10993-1.
Absorbent Material	Polyethylene	Unknown	The difference in material between the predicate device and the subject device was evaluated per ISO 10993-1.
Antimicrobial agent	70% Isopropyl Alcohol	70% Isopropyl Alcohol	No Difference
Site Use	Needleless Luer Access Valves	Needleless Luer Access Valves	No Difference
User population	Home and hospital use	Home and hospital use	No Difference
Packaging	Individual	Pole Strips	No Difference
Sterilization	Gamma Irradiated	Gamma Irradiated	No Difference
Additional Claims	This device does not contain natural rubber latex or Diethylhexylphthalate (DEHP).	This device is NOT made with Natural Rubber Latex. DEHP Free.	No Difference

8 – Non-Clinical Testing

The following bench tests were performed to evaluate the design elements and performance characteristics of the CapKlenZ and to demonstrate substantial equivalence to the predicate device. The CapKlenZ met the predetermined acceptance criteria. Tests results show that the CapKlenZ is substantially equivalent to the predicate device.

8.1- Performance Testing

Table 5.8.1 below provides a summary of the bench testing performed on CapKlenZ on baseline (T=0) and aged devices (T=2 years).

Table 5.8.1 Bench Testing performed on CapKlenZ

Test #	Test Name	Applicable Standard or Internal Test Method	Test Results	
1	Dimensional, physical and functional attributes	Internal Test Method	T=0 T=2	Pass
2	Disassembly Force	Internal Test Method	T=0 T=2	Pass
3	Air Leakage	Internal Test Method	T=0 T=2	Pass
4	Liquid Leakage	Internal Test Method	T=0 T=2	Pass
5	Packaging Integrity (Seal Peel Strength)	ASTM F88/88M-15	T=0 T=2	Pass
6	Packaging Integrity (Bubble Test)	ASTM F2096-11	T=0 T=2	Pass
7	Unscrewing Torque	ISO 594-2	T=0 T=2	Pass
8	Ease of Assembly	ISO 594-2	T=0 T=2	Pass
9	Resistance to Overriding	ISO 594-2	T=0 T=2	Pass
10	Stress Cracking	ISO 594-2	T=0 T=2	Pass
11	Shipping and Transit	ISTA 3A	T=0 T=2	Pass

8.2 – Antimicrobial Efficacy Testing

Star Mountain Medical, Inc. provided non-clinical performance test data in order to demonstrate the pre-defined acceptance criteria for a disinfecting device. This acceptance criteria is defined as a bacteria count reduction of ≥ 4 log of 2 selected gram positive bacteria, 2 selected gram negative bacteria, and 3 selected fungus/yeast micro-organisms for 3 time points from 3 minutes up to 60 minutes (1 hour).

Table 5.8.2 provides a summary of the antimicrobial efficacy testing performed on baseline (T=0) and aged devices (T=2 years).

Table 5.8.2 Antimicrobial efficacy testing performed on CapKlenZ T=0 and T=2.

Organism	Description	Acceptance Criteria (bacterial count reduction (ΔLog))	Time point exposure (bacterial count reduction (ΔLog))		
			3 minutes	5 minutes	60 minutes
Staphylococcus aureus	Gram Positive	≥4.0	Pass	Pass	Pass
Staphylococcus epidermis	Gram Positive	≥4.0	Pass	Pass	Pass
Escherichia coli	Gram Negative	≥4.0	Pass	Pass	Pass
Pseudomonas aeruginosa	Gram Negative	≥4.0	Pass	Pass	Pass
Candida albicans	Fungus/Yeast	≥4.0	Pass	Pass	Pass
Candida glabrata	Fungus/Yeast	≥4.0	Pass	Pass	Pass
Candida auris	Fungus/Yeast	≥4.0	Pass	Pass	Pass

8.3 – Microbial Barrier Testing

Microbial barrier testing was performed to demonstrate that the CapKlenZ acts as a physical barrier for microbial ingress under worst-case conditions using an external bioaerosol of *Pseudomonas aeruginosa.*

Table 5.8.3 below provides a summary of the microbial barrier testing performed on baseline (T=0) and aged devices (T=2 years).

Table 5.8.3 Microbial Barrier testing performed on CapKlenZ T=0 and T=2.

Organism	Description	Acceptance Criteria (% Microbial Ingress)	Time point exposure (% Microbial Ingress)		
			1 hour	24 hours	168 hours
Pseudomonas aeruginosa	Gram Negative	0	Pass	Pass	Pass

8.4 – Alcohol in the fluid path Testing

The amount of the alcohol that may leak into an attached IV line due to use of the CapKlenZ was evaluated using as reference the methodology described by Sauron et. al., 2015, *"Using isopropyl alcohol impregnated disinfection caps in the neonatal intensive care unit can cause alcohol toxicity"* and using a representative selection of different brands of needleless luer access valves in terms of materials and design. Alcohol quantification was measured by gas chromatography, observational data and functional data were performed as well to determine whether the CapKlenZ changed the appearance, and, or, the function of the needleless luer access valve.

Table 5.8.4 describes a summary of the Alcohol in the fluid path testing.

Table 5.8.4 Alcohol in the fluid path testing performed on CapKlenZ

Circuit Type	Temperature	Isopropyl alcohol dosage mean (mmol/L)	Visual Inspection	Functional Inspection
Active Circuits	23°C	0.00748	Pass	Pass
	35°C	0.00780	Pass	Pass
Passive Circuits	23°C	Not Applicable	Pass	Pass

8.5 –Discussion

The performance testing results demonstrated that the subject device is capable to perform as the predicate device for the intended use. The differences in diameter, height, reservoir, internal membrane, and absorbent material of the subject device compared to the predicate device were evaluated by conducting performance testing per ISO 594-2 and antimicrobial efficacy testing.

9 – Biocompatibility Testing

The CapKlenZ is classified as an "externally communicating device, blood path indirect, prolonged duration". Biocompatibility testing was performed in accordance with ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" (2009).
Table 5.9 below describes the testing performed to determine the biocompatibility.

Table 5.9 Biocompatibility Testing

Biological Effect	Test	Compliance Standard
Cytotoxicity	L929 MEM Elution	ISO 10993-5
Sensitization	Murine Local Lymph Node Assay	ISO 10993-10
Irritation or Intracutaneous Reactivity	Intracutaneous Injection Assay	ISO 10993-10
Acute Systemic Toxicity	Acute Systemic Injection Assay	ISO 10933-11
Pyrogenicity	Material-Mediated Rabbit-Pyrogen	ISO 10993-11
	Bacterial endotoxin testing (LAL)	ANSI/AAMI/ST72:2002
Hemocompatibility	Hemolysis (Indirect) in Rabbit Blood (ASTM Method)	ISO 10993-4
Subacute/Subchronic Toxicity	Subchronic IV Toxicity in mice Subacute IP Toxicity in mice	ISO 10933-11
Particulate Matters in Injections	Particulate Matters in Injections	USP <788>

10 - Sterilization Testing Summary

CapKlenZ is sterilized using a validated Gamma sterilization process which complies with ANSI/AAMI/ISO 1137-1:2006/(R) 2015&A1:2013 Sterilization of health care products – Radiation – Part 1: Requirements for development validation, and routine control of a sterilization process for medical devices, ANSI/AAMI/ISO 11137-2:2013 Sterilization of health care products – Radiation Part 2: Establishing the sterilization dose, and ANSI/AAMI/ISO 11137:2006 (R) 2010. Sterilization of health care products- Radiation-

Part 3: Guidance on dosimetric aspects. Packaging ensures that the fluid path contacting components are delivered sterile.

Table 5.10 below provides a summary of the sterilization performed on CapKlenZ.

Table 5.10 Sterilization Testing

Validation Sterilization Process	Sterility Assurance Level (SAL)	Validation Result
Gamma Radiation	10^{-6}	Pass

11 – Conclusion

The modifications to the design, dimensions, and materials of the subject device met the performance requirements. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.

The CapKlenZ is substantially equivalent to the DualCap Solo™ cleared under K123065 in intended use, target population, treatment method, use environment, and technological characteristics.