



August 18, 2022

STERIS Corporation
Mr. Carroll Martin
Regulatory Affairs Director
5960 Heisley Road
Mentor, Ohio 44060

Re: K222272

Trade/Device Name: truFreeze System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: July 29, 2022
Received: July 29, 2022

Dear Mr. Martin:

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 Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K222272

Device Name
truFreeze System

Indications for Use (Describe)

The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign (e.g. Barrett's Esophagus with high grade dysplasia and/or low grade dysplasia) and malignant lesions.

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 for the truFreeze System

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Mr. Carroll Martin
Regulatory Affairs Director
Tel: 440-358-6259
Email: Carroll_Martin@steris.com

Submission Date: July 29, 2022

1. Device Name

Trade Name:	truFreeze System
Device Class:	Class II
Regulation Name:	Cryosurgical Unit and Accessories
Common/usual Name:	Cryosurgical Unit
Regulation Number:	21 CFR 878.4350
Product Code:	GEH

2. Predicate Device

truFreeze System, K171626

3. Device Description

The truFreeze system is a cryosurgical tool that applies medical-grade liquid nitrogen to the ablation area via a small, low pressure, open tipped catheter. The truFreeze System consists of a console and a disposable spray kit.

The console is the central interface of the system and is comprised of a touch panel computer (TPC) and cryogen, suction, and electronics modules packaged in a mobile cart. Users interact with the console through a dual foot pedal and a touch panel. An off-the-shelf controller and associated software manage the cryogen level sensing, filling, pressure, cooling, defrost, suction, timing and data management functions. A fill kit, stored on the rear of the console, allows for liquid nitrogen transfer from the source tank to the console. Safety features include indicators, tank pressure relief valves, an isolated low voltage power system, and an emergency button to be used in the event of user or technical malfunction.

There are 2 types of spray kits available. One kit is available for active venting procedures and one is available for passive venting procedures. Both active and passive venting kits are provided in a carton of five (5) individually packaged sterile, single-use catheters with introducers (an introducer is a spring that is introduced into the accessory channel port of the endoscope to provide additional strain relief to the catheter during insertion and retraction from the endoscope) in individual pouches. These catheters are used to introduce the liquid nitrogen to the desired site.

Additionally, the active venting kit is provided with a carton of five (5) individually packaged sterile, single-use cryo decompression tubes (CDTs) with associated tubing in individual pouches. The CDTs are used for the removal of the gaseous nitrogen from the patient. Each carton within a spray kit contains the instructions for use.

4. Indications for Use

The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign (e.g. Barrett's Esophagus with high grade dysplasia and/or low grade dysplasia) and malignant lesions.

5. Technological Characteristics Comparison Table

A comparison of technical characteristics between the proposed and predicate devices is summarized in **Table 1**.

Table 1. Technological Characteristics Comparison Table

Features	truFreeze System Predicate Device K171626	Modified Device	Comparison
Intended Use	The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign (e.g. Barrett's Esophagus with high grade dysplasia and/or low grade dysplasia) and malignant lesions.	The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign (e.g. Barrett's Esophagus with high grade dysplasia and/or low grade dysplasia) and malignant lesions.	Identical
Construction	The truFreeze System consists of a console that is used to control the application of the cryogen, spray catheters, active and passive venting sets and cryodecompression tubing sets and connectors	The truFreeze System consists of a console that is used to control the application of the cryogen, spray catheters, active and passive venting sets and cryodecompression tubing sets and connectors	Identical
Sterile/Non-sterile	Non-sterile (console) Sterile (spray catheters and cryodecompression tube)	Non-sterile (console) Sterile (spray catheters and cryodecompression tube)	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterilization Assurance Level	10 ⁻⁶	10 ⁻⁶	Identical
Usage	Single Use: Spray catheters and cryodecompression tubing	Single Use: Spray catheters and cryodecompression tubing	Identical
	Reusable: Console	Reusable: Console	Identical
Principle of Operation to Achieve Cooling	Via pressurized liquid nitrogen (LN ₂)	Via pressurized liquid nitrogen (LN ₂)	Identical
Method to Destroy Tissue	Uses freeze/thaw/freeze cycle	Uses freeze/thaw/freeze cycle	Identical
Ability to Reach Equivalent Dose	Achieve a 4 cm ice ball within 12 min (total elapsed time)	Achieve a 4 cm ice ball within 12 min (total elapsed time)	Identical
Point Source for Destruction of Tissue	Catheter head	Catheter head	Identical
Liquid Nitrogen Capability to Freeze Tissue	-196°C	-196°C	Identical

Features	truFreeze System Predicate Device K171626	Modified Device	Comparison
Output Temperature at Catheter Tip	-196°C	-196°C	Identical
Equivalent Ice Formation	Able to produce an average 23.4 mm (radius measurement) ice ball within 5 minutes	Able to produce an average 23.4 mm (radius measurement) ice ball within 5 minutes	Identical
Equivalent Temperature Distribution	@ freeze depth of 21.87mm at 0°C -20°C isotherm at 15.5mm depth -40°C isotherm at 11.8mm depth	@ freeze depth of 21.87mm at 0°C -20°C isotherm at 15.5mm depth -40°C isotherm at 11.8mm depth	Identical
Delivery of Cryogen	A spray delivered through a 2.2mm (7 F) sterile conduit; straight catheter Controlled by user	A spray delivered through a 2.2mm (7 F) sterile conduit; straight catheter Controlled by user	Identical
Consistent delivery of cryogen controlled for target site	Computer driven	Computer driven	Identical
Guidance required for procedure	Direct visualization via an endoscope or bronchoscope	Direct visualization via an endoscope or bronchoscope	Identical
Safety Features /Mitigations	Users can stop dose at any time via foot pedal activation or emergency stop button	Users can stop dose at any time via foot pedal activation or emergency stop button	Identical
Features /Mitigations (catheter/probe)	Confirms use of a compatible catheter using RFID	Confirms use of a compatible catheter using RFID	Identical
Notifies physician to stop spraying	Audible beeper to coincide with visual display of timer.	Audible beeper to coincide with visual display of timer.	Identical
Computerized test of system prior to use	Uses computer program to test that system is properly operating before exposure of cryotherapy	Uses computer program to test that system is properly operating before exposure of cryotherapy	Identical
Computerized continuous monitoring of system during procedure	Uses computer program to abort freezing if a system failure is detected	Uses computer program to abort freezing if a system failure is detected	Identical
Ensure patient is not exposed to high pressure gases	Uses active suction pump and CDT, or a natural orifice, as per instructions for use. Instructions for Use provide venting guidance for proper gas egress	Uses active suction pump and CDT, or a natural orifice, as per instructions for use. Instructions for Use provide venting guidance for proper gas egress	Identical
Protect healthy tissue from excessive temperatures	Uses endoscope or bronchoscope to help insulate when using internally. Contains insulation outside of scope to protect user.	Uses endoscope or bronchoscope to help insulate when using internally. Contains insulation outside of scope to protect user.	Identical
Pressure Controls	Valves and pressure transducer to control pressure of liquid nitrogen (LN2); Redundant pressure switch; Mechanical Relief	Valves and pressure transducer to control pressure of liquid nitrogen (LN2); Redundant pressure switch; Mechanical Relief	Identical

Features	truFreeze System Predicate Device K171626	Modified Device	Comparison
Thermal/Defrost	Active defrost capability to thaw catheter using warm Nitrogen gas	Active defrost capability to thaw catheter using warm Nitrogen gas	Identical
Safe storage of cryogenic agent	Single Dewar tank	Single Dewar tank	Identical
Biocompatibility	Patient contact materials comply with ISO -10993	Patient contact materials comply with ISO -10993	Identical

6. Summary of Changes

The following is a summary of the changes in this submission:

- To take the previous instructions for use that contained instructions for both passive and active venting and separate it into two instructions for use: one for active venting and one for passive venting.
- Update the previous owner's manual

These changes were initiated for the following reasons:

- Transfer of the truFreeze device from CSA to STERIS
- Clarification of some information in the original instructions for use
- Addition of information for user convenience
- Standardization of information in accordance with STERIS instructions for use
- Formatting

None of the modified information is related to issues of device performance.

7. Summary of Non-Clinical Performance Testing

No performance testing was conducted as the subject of this submission is changes to the labeling only.

8. Conclusion

Based on the intended use and technological characteristics, the subject device is as safe and effective as the legally marketed predicate device (K171626).