December 2, 2022

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

Re: K223369
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: November 1, 2022
Received: November 4, 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,

Colin K. Chen -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223369

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary for the truFreeze System

STERIS Corporation
Manufacturer
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Tel: 440-358-6259
Email: Carroll_Martin@steris.com

Submission Date: November 1, 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, K222272

This submission is for a modification to the device that was the subject of K222272, the predicate device

## 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<br>Predicate Device K222272 | 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 cryo-decompression 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 cryo-decompression tubing sets and connectors | Identical |
| Sterile/Non-sterile | Non-sterile (console)<br>Sterile (spray catheters and cryo-decompression tube) | Non-sterile (console)<br>Sterile (spray catheters and cryo-decompression tube) | Identical |
| Sterilization Method | Ethylene Oxide | Ethylene Oxide | Identical |
| Sterilization Assurance Level | $10^{-6}$ | $10^{-6}$ | Identical |
| Usage | Single Use:<br>Spray catheters and cryo-decompression tubing | Single Use:<br>Spray catheters and cryo-decompression tubing | Identical |
| | Reusable:<br>Console | Reusable:<br>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<br>Predicate Device K222272 | 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<br>-20°C isotherm at 15.5mm depth<br>-40°C isotherm at 11.8mm depth | @ freeze depth of 21.87mm at 0°C<br>-20°C isotherm at 15.5mm depth<br>-40°C isotherm at 11.8mm depth | Identical |
| Delivery of Cryogen | A spray delivered through a 2.2mm (7 F) sterile conduit; straight catheter<br>Controlled by user | A spray delivered through a 2.2mm (7 F) sterile conduit; straight catheter<br>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.<br>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.<br>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<br>Predicate Device K222272 | 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 changes that are the subject of this submission are as follows:

- The 16 French (Fr) cryo-decompression tube has been redesigned to make it more robust. Stainless steel support wires have been added to make the tube substantially more robust, even during challenging procedures. This modification has also resulted in a change to the specification of the bend radius of the cryo-decompression tube specification from 3 inches to 1.5 inches to reflect an improvement in stability.

The changes were initiated for the following reasons:

- Redesign to the 16Fr cyro-decompression tube is being conducted due to customer feedback that the device required careful handling.

## 7. Summary of Non-Clinical Performance Testing

For the redesign of the 16 Fr cryo-decompression tube, the following verification testing was conducted:

| Test | Result |
|---|---|
| Suction flow rate | Pass |
| Kink Resistance | Pass |
| Dimensional measurements | Pass |
| Tensile strength of bonded joints | Pass |
| Biocompatibility testing | Pass |
| Product sterility adoption | Pass |
| Simulated use testing | Pass |

## 8. Conclusion

Based on the intended use and technological characteristics, the subject device is as safe and effective as the legally marketed predicate device (K222272).