**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

CSA Medical Incorporated
Ms. Sherrie Coval-Goldsmith
Vice President Regulatory Affairs/Quality Assurance
91 Harwell Avenue
Lexington, Massachusetts 02421

October 14, 2015

Re: K152668
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: September 16, 2015
Received: September 17, 2015

Dear Ms. Coval-Goldsmith:

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. 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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K152668

Device Name
truFreeze® System

Indications for Use (Describe)

The truFreeze® System is intended for cryogenic destruction of tissue requiring either active or passive venting during surgical procedures.

The truFreeze® System is Indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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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."

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# Attachment D – 510(k) Summary (truFreeze® System)

| | |
|---|---|
| Applicant | CSA Medical |
| Establishment Registration Number | 3004534508 |
| Contact Person | Sherrie Coval-Goldsmith<br>Vice President RA/QA<br>CSA Medical<br>91 Hartwell Ave<br>Lexington, Ma 02421<br>Phone: 781-538-7447<br>Fax: 781-538-4730<br>sgoldsmith@csamedical.com |
| Summary Date | September 16, 2015 |
| Proprietary Name | truFreeze® System |
| Classification | Class II |
| Classification Name | Cryosurgical Unit, Cryogenic Surgical Device |
| Regulation Number | 21 CFR 878.4350 |
| Classification | Product Code GEH |
| Predicate Device | K143625 (truFreeze System) |

**Device Description**

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

**Console**:

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 wireless remote control provides alternative timer control from a distance in the treatment room. 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.

**Disposable spray kit**:

There are no proposed changes to the disposable spray kit. 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 include are provided in a carton of five (5) individually packaged sterile, single-use catheters with introducers in individual pouches. Additionally, the active venting kit is provided with includes a carton of five (5) individually packaged sterile, single-use CDTs with associated tubing in individual pouches. Each carton within a spray kit contains the instructions for use.

**Labeling (Intended Use/Indications for Use and Instructions for Use Document)**

The truFreeze System is identical in its Intended Use as the predicate device (K150920 truFreeze system). Both devices describe the ablation of benign and malignant tissue in general terms and the requirement to use either active or passive venting during surgical procedures. Both devices are indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign and malignant lesions. This is the same indication for use as previously cleared for the previous version of the truFreeze System (K150920).

**Technical and Operational Characteristics**

This 510(k) implements a design modification to the surface finish and depth of the bore where the seal is seated in the receptacle body. These modifications consisted of (1) improving the finish of the surface that contacts the seal OD from a lower to a smoother finish and (2) tightening the counterbore depth dimension to ensure compression of the cryo seal flange by the mating collar. The proposed modifications are tighter than the current specifications, but still fall within the current range of these two specifications.
Other than this specification modification, the technical and operational characteristics of the truFreeze System are unchanged.

**Testing**

The truFreeze System was previously subjected to a comprehensive test program that included electrical safety and electromagnetic compatibility test, software tests, animal testing, biocompatibility and sterilization testing. The proposed modifications were tested in CSAM's verification testing.

Components were built to the smoother surface finish as well as at both ends of the proposed modified depth specification. Two parts at each end of the specification were tested. Testing at the low and high end modified depth specification confirmed that performance was acceptable across the entire tolerance range. Fill testing was performed to subject the transfer blocks to multiple fill cycles, to confirm that leaking would not result with the proposed changes to the specifications. Each transfer block was subjected to 6 fills, or 3 times the number of fills when the leaks occurred. No leaks were observed across multiple fills, nor did they introduce any new safety concerns as the receptacle body performed as intended. All acceptance criteria were met. Therefore, the proposed specification modifications are considered verified.

**Table 1.** Summary of Test Results

| Transfer Interface Assembly Sample # | Leaking Result | Acceptance Criteria | Pass/Fail |
|---|---|---|---|
| B-1 (Low end of depth spec) | No leaking observed | No leaking observed | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| B-2 (Low end of depth spec) | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| C-1(High end of depth spec) | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |

| | | | |
|---|---|---|---|
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| C-2(High end of depth spec) | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |
| | No leaking observed | | PASS |

**Rationale For Substantial Equivalence**

The labeling as well as the technological characteristics of the proposed truFreeze System and the predicate device (K150920 truFreeze system) were compared. The Intended Use/Indications for Use statement of the two devices had identical general claims and do not raise new questions of safety and performance. The proposed changes to the technology were compared and are identical. The specification changes fall within the current specifications and are considered a tightening of the specifications. The tightening of the specifications will address complaints of cryogen leak occurring during the filling of the truFreeze system prior to system use and do not raise new questions of safety and performance.

**Conclusion**

Based on the comparison of labeling, technology and verification testing comparisons, the truFreeze device is substantially equivalent to the predicate device listed above.