



Food and Drug Administration
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October 25, 2016

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

Re: K162695
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 27, 2016
Received: September 29, 2016

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 Part 801); 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" (21 CFR 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,

Jennifer R. Stevenson -

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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

Indications for Use

510(k) Number (if known)

K162695

Device Name
truFreeze® System

Indications for Use (Describe)

Intended Use

The truFreeze System is intended for cryogenic destruction of tissue using Liquid Nitrogen spray that has a boiling point of -196°C requiring either active or passive venting during surgical procedures.

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 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.

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510(k) Summary (truFreeze® System)

Applicant	CSA Medical
Establishment Registration Number	3004534508
Contact Person	Sherrie Coval-Goldsmith, M.S. Vice President RA/QA CSA Medical 91 Hartwell Ave Lexington, Ma 02421 Phone: 781-538-7447 Fax: 781-538-4730 sgoldsmith@csamedical.com
Summary Date	26 September 2016
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	K161557 (truFreeze System)

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.

Console:

There are no proposed changes to the 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 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 stop button to be used in the event of user or technical malfunction.

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 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 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. There is a proposed change to the active venting disposable spray kit. The proposed change reduces the Outside Diameter (OD) of the CDT from 20 French to 16 French without changing performance specifications, adds additional Marker Bands to the 16 French version of the CDT and makes the 16 Fr CDT and 20 Fr CDT available as a 5-pack box in addition to as a part of the active venting kit.

Intended Use/Indications for Use and Instructions for Use

The truFreeze System is identical in its Intended Use and Indication for Use as the predicate device (K161557 truFreeze system).

Both the predicate device and the proposed device are intended for cryogenic destruction of tissue using Liquid Nitrogen spray that has a boiling point of -196°C requiring either active or passive venting during surgical procedures.

Both the predicate device and the proposed device are indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign and malignant lesions.

These are the same Intended Use and Indication for Use as the previously cleared version of the truFreeze System (K161557).

The Instructions for Use and the Operator's Manual require modification to reflect the availability of a 16 Fr OD CDT and the addition of two (2) Marker Bands to the 16 Fr CDT.

Technical and Operational Characteristics

The truFreeze System is similar in design, hardware and software, as well as operational and technological characteristics as the predicate device. No new safety concerns are being raised by the reduction in the CDT OD, additional Marker Bands or 5-Pack Configurations.

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 do not require repeating these tests.

The proposed reduction in CDT OD and addition of Marker Bands were subjected to CSA's verification and validation testing processes.

Table 1. Summary of Test Results

Proposed Change	Test Specification	Result
Reduce CDT OD	The CDT shall be less than or equal to 16.5 Fr	Pass
	The CDT shall not crack, break or experience lumen separation after exposure to temperatures with the boundary range of - 196°C and 40°C.	Pass
	Shall have sufficient column strength to allow it to be advanced over a 0.072" Savary Wire	Pass
	Shall maintain structural integrity and not kink while looped in a minimum internal bend radius.	Pass
	A complete flex of the CDT shall meet current kinking specification.	Pass
	The bonded CDT connector will withstand a minimum of 10lbf pull force without failing.	Pass
	Flow Rate shall meet current specification.	Pass
	The CDT OD shall not deform per specification.	Pass
	The bonded CDT connector will shall meet current. pull force specification without failing	Pass
Enhance Visualization	Circumferential banding must be sufficient to identify the banding through an endoscope.	Pass
	Shall be labeled with four side-by-side 0.100"±0.030" wide identifying bands 7.7" ±0.1" from the distal end.	Pass
	All 0.100" wide bands shall be 360 degrees	Pass

Summary of Design Validation Testing Completed			
Proposed Change	Test Specification	Result	Protocol Report
Reduce CDT OD	CDT diameter will be as small as possible while enabling gas egress and allowing it to pass through the majority of anatomies with and without dilation	Pass	PRO-R-17-00193 User Survey / Simulated Use
			PRO-R-17-00198 Animal Study
Enhance Visualization	CDT will have Mark Bands to assist user for performing the initial, approximate placement of the CDT	Pass	PRO-R-17-00193 User Survey / Simulated Use

Rationale For Substantial Equivalence

The proposed changes do not affect the Indications for Use of the truFreeze System or alter the fundamental scientific technology of the device compared with the predicate device. They do not introduce any new safety or efficacy questions.

The company, through its design control activities, has determined that clinical data are not necessary to evaluate safety and effectiveness related to this change and that the results of design validation do not raise new issues of Safety or Effectiveness. Consequently, in the opinion of the company, the truFreeze System, incorporating the reduced French Size, additional Marker Bands, 5-Pack unit boxes and updated Operator's Manual, IFU and Product Labels, is substantially equivalent to the predicate device.

Conclusion

Based on the comparison of labeling, technology and verification testing comparisons, the truFreeze device is substantially equivalent to the predicate device K161557.