DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 26, 2016

CSA Medical, Inc.
Ms. Sherrie Coval-Goldsmith
VP of Regulatory & Quality
91 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K161557
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: May 27, 2016
Received: June 6, 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,

Christopher J. Ronk -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 on last page

510(k) Number *(if known)*
K161557

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^{0}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)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

Applicant	CSA Medical, Inc
Establishment Registration Number	3010140265
Contact Person	Sherrie Coval-Goldsmith, MS 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	May 27, 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	K160273 (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:
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.

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. The disposable kit is the same as previously cleared for the predicate truFreeze System (K160273). Therefore, there are no new issues of safety or effectiveness raised.

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

There are no proposed changes to the Intended Use/Indications for Use statement. The truFreeze System is intended for cryogenic destruction of tissue using Liquid Nitrogen spray that has a boiling point of -196^{0}C 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. This is the same indication for use as previously cleared for the previous version of the truFreeze System (K160273).

Technical and Operational Characteristics

This 510k implements software and hardware modifications to: 1) minimize procedural disruptions and user annoyance; 2) implement hardware manufacturability improvements and 3) correct a discrepancy in the operator's manual.

The software is designed to send a Terminal Error message to alert the user to stop a procedure if a potential safety issue (stemming from a communication error) occurs while in the Procedure code, of an issue in Fill code occurs and to take additional actions.

However, within the Procedure code are non-spraying states which carry no risk to the patient. In these situations, following the actions prompted by the current message results in unwarranted procedural disruption. A modification to the software will provide state specific instructions on the GUI to allow the user to take appropriate actions with minimal disruption during a procedure. A state specific Terminal Error message will also be modified in the Fill Code, which like the non-spray states has no effect on patient safety. Additionally, by reducing the sampling rate for communication errors during non-spray Procedural states, the number of Terminal Error messages should be reduced.

Additionally, Terminal Errors may occur as a result of loose hardware connections. Hardware modifications will be implemented to make connections more rugged and resistant against loosening.

Other software modifications include: 1) elimination of a beep sound associated with an unsuccessful scan of the catheter's RFID tag or a scan of an expired tag (the beep sound associated with a successful scan remains) and 2) permit more time during the BIT pressure sensor test to mitigate situations where tank pressure may be low for an extended period of time (e.g. fill), allowing more time to build the tank pressure required to pass the BIT test. These two modifications are intended to provide more clarity to the user in the use of the system and to reduce user annoyance.

Hardware that is not available for use by the user was removed to improve manufacturability. The current UFD is no longer available for purchase by the manufacturer and is being replaced with another UFD with the same storage capacity.

There is a reference within the Operator's manual to filling the truFreeze System from a 22PSI source tank and from a <50PSI source tank within the manual. To eliminate confusion, the <50PSI reference will be modified to <30 PSI, 22PSI recommended. This clarification meets the current specification and reflects currently available medical grade LN2 source tanks.

Other than these modifications, 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 testing, software testing, animal testing, biocompatibility and sterilization testing and is not being repeated. Verification testing to support the proposed hardware and software modifications in this submission was performed.

Currently there are two truFreeze software load packages in the field to support two different level sensing configurations, C-Stic level sensing and Load Cell level sensing. Since the currently released software is functioning as intended, and do not affect safety or efficacy of the system, the proposed modifications within this submission will only be available for the truFreeze console design containing the truFreeze C-stic software load package and C-Stic level sensing.

Three consoles were tested with the proposed hardware and software modifications. The software modification was validated via software regression testing, software integration testing and system functional testing.

CSA Software Load Package Regression Tests:

Regression testing was successfully completed and all tests passed, verifying that the updates did not negatively impact the code. No safety or functionality concerns were observed during testing.

CSA Software Load Package Integration Tests:

All integration tests were completed and were considered acceptable. The successful completion of these tests demonstrate the ability of the software to correctly detect cDAQ related hardware and communication errors and display the applicable terminal or system error message. The removal of the Remotes test in BIT and the removal of the beep and initiation of precool after an unsuccessful scan was successfully verified. No safety or functionality concerns were observed during testing.

CSA Software Load Package Unit Testing:

Unit tests were used to verify the BIT and code revision updates. Regression and Unit test results were determined solely by the code and the ini file values and were not system or run dependent. Therefore, only one run on one console is required for this testing. Unit testing was successfully completed and all tests passed, verifying that the updates did not negatively impact the code. No safety or functionality concerns were observed during testing.

CSA Hardware Stress Testing:

Three production equivalent systems underwent stress testing demonstrating that the proposed hardware modifications were robust. The shock testing was used to demonstrate the robustness of hardware modifications simulating transport to and from a fill location once per week for the total useful life of the product (5 years). In addition, the Panel PC was rotated back and forth and up and down repeatedly, to verify range of motion. Three consoles were used to account for typical

console to console variability. All testing was successful and no safety or functionality concerns were observed.

trufreeze System Functional Tests

Functional testing was successfully performed and passed confirming that the software updates implemented did not negatively impact system performance and functionality. System functional testing was performed on three production consoles to demonstrate that the software updates implemented did not impact system performance and functionality. The console Field Verification test was conducted on each console using the steps and methods required for field installations to confirm that the system was functioning as intended. Three consoles were used to account for any typical console to console variability. No safety or functionality concerns were observed with any functional tests.

Verification Testing Summary Table				
Test Type		Proposed truFreeze System	Predicate truFreeze System (K150920)	Comments
Software Regression Tests	BIT Code	Pass	Pass	Equivalent
	Fill Code	Pass	Pass	Equivalent
	Procedure Code	Pass	Pass	Equivalent
	Data Code	Pass	Pass	Equivalent
	Service Code	Pass	Pass	Equivalent
	Admin Code	Pass	Pass	Equivalent
	Home Code	Pass	Pass	Equivalent
Software Integration Tests	Fill Code	Pass	NA	The integration tests were specific to the proposed modifications and therefore it was not part of K150920
	Procedure Code	Pass	NA	The integration tests were specific to the proposed modifications and therefore it as not part of K150920

System Functional Tests	truFreeze Field Verification	Pass	Pass	Equivalent
Hardware Stress Tests	Simulated Shock and Rotation Testing	Pass	NA	The simulated shock and rotation methods were not part of K150920 testing.

Rationale For Substantial Equivalence

The labeling as well as the technological characteristics of the proposed truFreeze System and the predicate device (K160273 truFreeze system) were compared. The Intended Use/Indications for Use statement of the two devices are identical and do not raise new questions of safety and performance. The proposed changes to the hardware and software enhance the safe use of the device by: 1) providing additional levels of control against the risk of loss of communication; 2) providing clarifying state-dependent information to the user if an error message is received to assist them in clearing the error messages; 3) clarifying a discrepancy in the source tank fill pressure found within the operator's manual and 4) eliminate a redundant beep sound relating to an unsuccessful scan of the catheter. These modifications are intended to minimize disruption to a procedure and to minimize user annoyance or confusion, while maintaining safety for the patient.

Verification and validation testing demonstrate that the software and hardware modifications do not raise new questions of safety and performance.

Conclusion

Based on the label and technology comparison as well as the performance testing, the Proposed truFreeze device is substantially equivalent to the predicate device listed above.