



Food and Drug Administration  
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June 17, 2015

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

Re: K150920

Trade/Device Name: truFreeze<sup>®</sup> System  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: Class II  
Product Code: GEH  
Dated: April 6, 2015  
Received: April 6, 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 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" (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,

  
**Jennifer R. Stevenson -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

Indications for Use

510(k) Number (if known)  
K150920

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

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

K150920 (page 1/3)

Applicant	CSA Medical
Establishment Registration Number	3004534508
Contact Person	Sherrie Coval-Goldsmith 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	April 3, 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. The truFreeze disposable spray kit continues to consist of five (5) individually packaged sterile single-use catheters (7 Fr Straight Tip Catheter and one Catheter Introducer) and 5 individually packaged cryogen decompression tubes (CDTs) (each containing one Dual Lumen 20 Fr CryoDecompression Tube (CDT), Connector, and Suction Tubing). The catheter is flexible and capable of retroflex in a scope. The CDT and accessory tubes are included for use with the on-board suction system.

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

The truFreeze System is identical in its Intended Use as the predicate device (K143625 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 (K143625).

**Technical and Operational Characteristics**

This 510(k) implements a software modification to incorporate a control that will detect and respond to communication interruptions or failures with the internal cDAQ chassis and associated modules. Detecting and responding to communication interruptions or failures during the RUN cycle prevents the system from delivering an excessive rate of cryogen flow to the target area. Specifically, the two commercially available load packages were updated with additional error detection capabilities to:

1. Identify cDAQ related hardware and communication errors
2. Lockout and notify the user from the SW interface if these failures occur
3. Send a signal to close applicable valves.

Other than this additional software control, 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. Two sets of testing were performed for each of the load packages available to customers. Three consoles were successfully loaded with the respective load packages. 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 additional 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 (or not) cDAQ related hardware and communication errors and respond accordingly.

**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.

After successfully completing the regression testing, integration testing, and console field verification, the following items have been successfully verified and validated:

- The software functions as intended per software performance specifications
- All input and output software values are as specified
- The system functions as intended
- The software functions as intended when a cDAQ hardware error is present or not present.

Verification Testing Summary Table				
Test Type		Proposed truFreeze System (K150920)	Predicate truFreeze System (K143625)	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
Integration Tests	Fill Code	Pass	NA	The integration tests were specific to the K150920 and therefore it was not part of K143625 testing.
	Procedure Code	Pass	NA	The integration tests were specific to the K150920 and therefore it was not part of K143625 testing.
System Functional Tests	truFreeze Field Verification	Pass	Pass	Equivalent

#### **Rationale For Substantial Equivalence**

The labeling as well as the technological characteristics of the truFreeze System K150920 and the predicate device (K143625 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 software enhance the safe use of the device by providing additional controls. This provides a control that will detect and respond to communication interruptions or failures with the internal cDAQ chassis and associated modules. Verification and validation testing demonstrate that the software modification does not raise new questions of safety and performance.

#### **Conclusion**

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