

JUN 19 2014

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*Freeze disease**

CSA Medical Inc.
 91 Hartwell Avenue
 Lexington, MA 02421
 781.538.4720 tel
 781.538.4730 fax

510K Summary TruFreeze® System

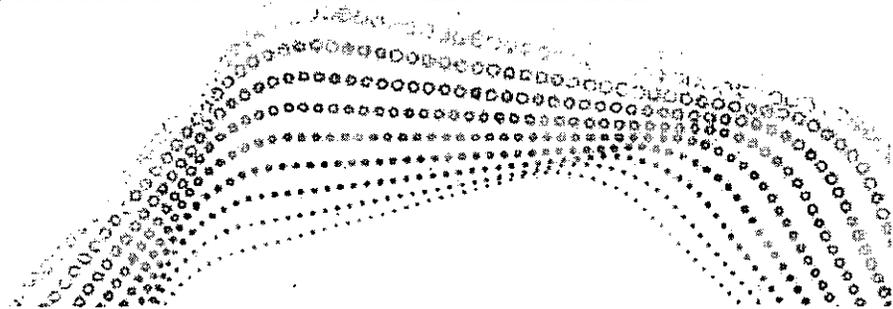
Applicant	CSA Medical
Establishment Registration Number	3004534508
Contact Person	Sherrie Coval-Goldsmith VP RA/QA CSA Medical 91 Hartwell Ave Lexington, Ma 02142 Phone: 781-538-7447 Fax: 781-538-4730 sgoldsmith@csamedical.com
Summary Date	June 9, 2014
Proprietary Name	truFreeze® System
Classification	Class II
Classification Name	Cryosurgical Unit, Cryogenic Surgical Device
Regulation Number	21 CFR 878.4350
Classification	Product Code GEH
Predicate Device	K102360 IceSense3

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 (1) a console and (2) 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:

The truFreeze disposable spray kit consists of 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.

Intended Use/Indications for Use

The truFreeze System is similar in its Intended Use as the predicate device (K102360 IceSense3). Both devices describe the ablation of benign and malignant tissue in general terms.

The requirement to use active or passive venting is in the cleared truFreeze Instructions for Use document (K113021) and adding it to the intended use/indications for use statement highlights the importance of venting and will enhance safe use of the device. Therefore, the revised intended use/indications for use statement raises no new issues of safety or effectiveness.

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

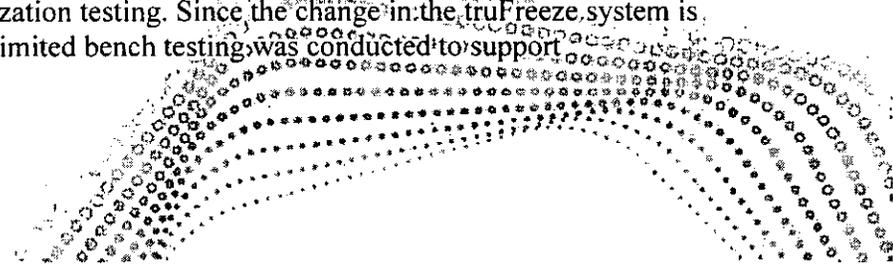
The truFreeze is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign and malignant lesions.

Technical and Operational Characteristics

The truFreeze System is similar in design, operational and technological characteristics as the predicate device and supports that no new safety concerns are being raised by change in intended use/indications for use statement and thus raises no new issues of safety or effectiveness.

Summary of 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. Since the change in the truFreeze system is limited to the Indications for Use, limited bench testing was conducted to support



demonstration of substantial equivalence in performance from the truFreeze to its predicate device. A summary table of the bench testing is provided below:

Bench Testing Comparison Table			
Bench Test Characteristic	Proposed truFreeze System (K133258)	Predicate IceSense3 (K102360)	Comments
Ability to reach equivalent dose (using same freeze/thaw/freeze cycle)	2min/2min/2min =1.8-2.4cm 3min/2min/3min=2.4-3.0cm 4min/4min/4min=3.0-3.6cm	2min/2min/2min =2.1-2.5cm 3min/2min/3min=2.6-3.0cm 4min/4min/4min=3.1-4.0 cm	Both capable of producing equivalent depth of ice
Output Temperature at tip	-196 degree C	-170 degree C	Both achieve temperatures low enough to destroy malignant tissue
Equivalent temperature distribution using the radial distance from the 0° C isotherm (border of ice ball) to the -20°C, -40°C and -50°C isotherms	@ freeze depth of 21.87mm at 0°C -20°C isotherm at 15.5mm depth -40°C isotherm at 11.8mm depth	@ freeze depth of 22mm at 0°C -20°C isotherm at 16.9mm depth -40°C isotherm at 13.4mm depth	Both can produce lethal ice at comparable depths

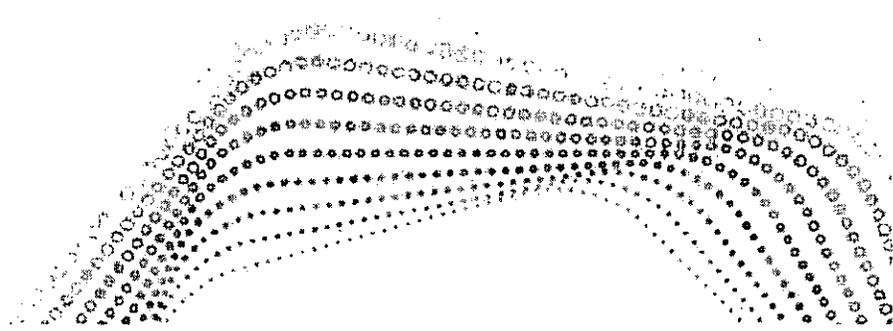
Rationale For Substantial Equivalence

The Intended Use/Indications for Use statement and technological characteristics of the truFreeze System and the predicate device (K102360 IceSense3) were compared. The Intended Use/Indications for Use statement of the two devices had equivalent general claims and do not raise new questions of safety and performance. Bench testing demonstrated that both devices can achieve equivalently cold temperatures in equivalent time periods to produce equivalent amounts of ice. These temperatures are cold enough to destroy unwanted benign or malignant tissue. This proposed change to the Indications for Use is well supported by a review of the peer reviewed clinical literature and are similar to those of the predicate device with the same general intended use of cryogenic destruction of benign or malignant tissue during surgical procedures.

The truFreeze device requires either active or passive venting for safe use. This is described within the previously cleared Instructions for Use document for the truFreeze device. The addition of this statement to the Intended Use/Indications for Use statement enhances the safe use of the device.

Conclusion

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





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 19, 2014

CSA Medical
Ms. Sherrie Coval-Goldsmith
Vice President, Regulatory Affairs/Quality Assurance
91 Hartwell Avenue
Lexington, Massachusetts 02142

Re: K133258

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 15, 2014
Received: May 16, 2014

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,

David Krause -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)
K133258

Device Name
truFreeze® System

Indications for Use (Describe)

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

The truFreeze 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)

Joshua C. Nipper -S

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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