DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 25, 2016

CSA Medial, Inc.
Ms. Sherrie Coval-Goldsmith
Vice President of Regulatory & Quality
91 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K160273
Trade/Device Name: truFreeze System
Regulation Number: 21CFR 878.4350.
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February 2, 2016
Received: February 2, 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 -A

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)*

K160273

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.

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510(k) SUMMARY- K160273

Applicant	CSA Medical, Inc
Establishment Registration Number	3010140265
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@csamedlcal.com
Summary Date	February 2, 2016
Proprietary Name	truFreeze® System
Classification	Class II
Classification Name	Cryosurgical Unit, Cryogenic Surgical Device
Regulation Number	21CFR 878.4350
Classification	Product Code GEH
Predicate Device	K152668 (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 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.

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.

The truFreeze System adds information to the Intended Use/Indications for Use statement regarding the use of liquid Nitrogen spray. This information is currently located within the predicate device Instructions for Use document and Operator's manual. Other than this modification, the Intended Use/Indications for Use statement is identical in its Intended Use as the predicate device (K152668 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 (K152668).

Adding the name of the cryogen being delivered; its boiling point temperature; the delivery of the cryogen in the form of a spray; highlights important information currently found within the current Instructions for Use and Operator's Manual documents into a prominent location of the label. The intent of this modification is to enhance safe use of the device by making the information readily available to the user. Therefore, the revised intended use/indications for use statement raise no new issues of safety or effectiveness.

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 and adds to it information currently present in truFreeze System labeling, no additional testing was performed.

Rationale For Substantial Equivalence

The Intended Use/Indications for Use statement and technological characteristics of the truFreeze System and the predicate device (K152668) 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. A comparison of the instructions for use document, operator's manual and performance documents demonstrated that both devices use liquid nitrogen spray that has a boiling point property of -196°C. The proposed changes to the Intended Use statement 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 tissue requiring either active or passive venting during surgical procedures.

The addition of this information to the Intended Use/Indications for Use statement enhances the safe use of the device by making information readily available to the user relating to the cryogen being delivered.

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.