DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 27, 2017

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

Re: K172041
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: July 5, 2017
Received: July 6, 2017

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,

Jennifer R. Stevenson -S3

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 below.

510(k) Number *(if known)*
K172041

Device Name
truFreeze ® System

Indications for Use *(Describe)*
The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign (eg. Barrett's Esophagus with high grade dysplasia) 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K172041

510(k) SUMMARY

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@csamedical.com
Summary Date	July 5, 2017
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	K163244 (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 Kits:

Currently, there are 2 types of spray kits available. One kit is available for active venting procedures and one kit is available for passive venting procedures. Both active and passive venting kits are provided in a carton of five (5) sterile, single-use catheters with introducers in individual pouches. Additionally, the active venting kit includes a carton of five (5) sterile, single-use, dual-lumen Active Venting Cryo Decompression Tubes (CDTs) with associated tubing in individual pouches. Each carton within a spray kit contains Instructions for Use.

CryoDecrompression Tube (CDT):

Proposed changes involve the CryoDecrompression Tube (CDT) only. The CDT is a necessary part of the truFreeze Active Venting Kit to suction gas out of the patient when liquid nitrogen is sprayed.

User Feedback suggests that some physicians experience significant space constraints within their procedure room resulting in the need to bend (portion of the tube that is outside the mouth) an excessive amount to get the CDT out of their way due to this space constraint. By moving the tube out of the way, the physician has more freedom to move during the ablation procedure. This excessive bending could result in a pinching of the tube leading to a transient increase in vacuum pressure in the absence of the cryospray that may be perceived as a physical obstruction. This is manifested by an optical color display of orange on the GUI. If this pinch created by the excessive bend is minimized by moving the tube, the orange indicator color disappears. Despite this appearance of the orange indicator display on the GUI, the CDT is performing as intended and is evacuating the gas as intended. This has led to some user annoyance. Additionally, User Feedback suggests that the weight of the suction tubing at the location of the console may also weigh down the CDT, depending upon tube position, resulting in the same pinching and orange indicator display described above.

Therefore, this Special 510k covers 2 CDT modifications:

1) decrease the durometer of the current Pebax shaft material to resist excessive bending forces of the CDT and increase the robustness of the CDT

2) create a bump extrusion to allow for a bump up in the current size of the proximal segment of the CDT (located outside the mouth).The bump does not modify the 16 Fr portion within the body but increases to 20Fr external to the body. This configuration reduces the likelihood of pinching outside of the oral cavity due to greater flexural strength of the 20 Fr section.

This design not only resists forces resulting in bending of the CDT but maintains the current gas egress flow performance specification.

These modifications address the user annoyance and provide the physician additional space (outside the patient's body) during the cryogenic procedure. Therefore, the minor technological modifications do not change the intended use or indications for use of the device and no new questions of safety or performance are raised.

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

The Intended Use/Indications for Use statements are identical to the predicate device. The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign (e.g. Barrett's Esophagus with high grade dysplasia) and malignant lesions.

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 (K163244).

Technical and Operational Characteristics

The truFreeze System, with the exception of the proposed CDT changes in durometer and dimension, is identical in design, operational and technological characteristics as the predicate device.

The bump extrusion and the decreased durometer of the CDT modifications reduce user annoyance by providing additional space and freedom to move during the cryogenic procedure and eliminate the indicator display that there is an obstruction during the non-spraying portion of the ablation procedure. Therefore, the minor technological changes do not change the intended use or indications for use of the device and no new questions of safety or performance are raised.

The fundamental technological characteristics is unchanged between the predicate device and the proposed device. There are no changes to the console or software.

The proposed modifications do not alter the principles of operation. The principle of operation is still to destroy unwanted tissue using a cryogenic agent. No change to the energy output or flow rate occurs. Therefore, the proposed modification still permits the device to destroy unwanted tissue. There are no new safety or performance questions raised with this proposed modification, therefore the proposed CDT is substantially equivalent to the CDT described in K163244.

Summary of Testing

Specification Test associated with proposed modifications	Result
Measure the maximum OD of the CDT	PASS The CDT OD measurement was Less than or equal to 16.5F (0.22 inches)
Bend Test	PASS All samples maintained structural integrity and no kinks observed.
Kink Resistance Test	PASS All samples endured a complete flex of the CDT without a fracture

Specification Test associated with proposed modifications	Result
Gas Egress Flow Rate	PASS All samples passed the minimum required LPM requirement at 3 inHg
CDT OD deformation with suction test	PASS The CDT OD did not deform at the minimum required % at 3 inches of mercury (inHg) of vacuum
Biocompatibility	All materials were determined to be biocompatible
Sterility	Sterility adoption was accepted
Accelerated Aging	Pass A 6 month shelf life is supported.
Packaging	PASS

The requirements specified have been successfully met, therefore the proposed modifications have completed design verification in accordance with the specifications.

The truFreeze System was previously subjected to a comprehensive test program that included electrical safety and electromagnetic compatibility testing, software testing, animal testing, therefore, those tests

are not being repeated. Verification testing to support the proposed catheter modification in this submission was performed.

Rationale for Substantial Equivalence:

The proposed changes do not affect the Instructions 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 these changes and that the results of design validation do not raise new issues of safety and effectiveness. Consequently, in the opinion of the company, the truFreeze System, lower durometer material and bump extrusion design, is substantially equivalent to the predicate device.

Conclusion

The proposed modifications do not change the Intended use or indications for use and the principles of operation of the truFreeze® System are unchanged. The modifications are limited a decreased durometer and an added bump extrusion to the CDT. These insignificant modifications do not affect the technological characteristics or intended use of the truFreeze System. This proposed modification is accomplished while maintaining the fundamental technological characteristics of the system. These modifications address user feedback.

These differences do not present any new issues of safety or effectiveness. Thus, the proposed truFreeze System and the predicate truFreeze System subject of K163244 are substantially equivalent.