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

July 14, 2017

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

Re: K171522
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 12, 2017
Received: May 25, 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 on last page

510(k) Number *(if known)*
K171522

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, 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	May 12, 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	K162695 (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 CryoDecompression Tubes (CDTs) with associated tubing in individual pouches. Each carton within a spray kit contains Instructions for Use.

This 510(k) introduces a third Spray Kit to the truFreeze System, referred to as the Rapid AV Spray Kit. These catheters provided with the proposed truFreeze System are only to be used for active venting procedures and have been modified to shorten the time it takes to pre-cool the catheter so it can achieve frost quicker.

The proposed Rapid AV Spray Kit consists of a carton with five (5) sterile, single-use catheters with introducers in individual pouches. Additionally, the Rapid AV Spray Kit includes a carton of five (5) sterile, single-use, dual-lumen Cryo- Decompression Tubes (CDTs) with associated tubing in individual pouches. Each carton within a spray kit

contains Instructions for Use. The CDTs are the same as previously cleared for the predicate truFreeze System (K162695).

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 intended for cryogenic destruction of tissue using Liquid Nitrogen spray that has a boiling point of-196°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 (K162695).

Since the proposed Spray Kit will be used for active venting only, the instructions for use document will not contain information required for passive venting procedures. Additionally, a precaution statement was added to remind the user that the catheter should not be used for passive venting or low flow procedures and a reminder to ensure that the correct catheter was being used. Additionally, the colors on the product label have been changed to help distinguish the Rapid AV catheter from the predicate spray kits.

The outside diameter (OD) measurement unit of the catheter label has changed from a unit of French (Fr) to a unit of mm to support current measurement conventions. This is also reflected in the Operator's Manual.

Technical and Operational Characteristics

The truFreeze System, with the exception of the Liquid Nitrogen delivery catheter, is identical in design, operational and technological characteristics as the predicate device.

The catheter materials have changed to provide a more efficient heat transfer. This shortens the time required to pre-cool the catheter so that it can achieve frost quickly. The process of pre-cooling the catheter occurs prior to initiating the timer, which signifies the initiation of the dosimetry. There are no changes to the amount of cryogenic energy delivered or the flow rate and there are no changes to dosimetry. Other minor changes to the catheter design are required to support the stainless-steel material, address user feedback, and to distinguish the Rapid Active Venting catheter from the predicate catheter. These include: 1) use of a laminated metal to enhance heat transfer; 2) change in bayonet material to provide for patient isolation; 3) dimensional changes from material changes affecting the bayonet; 4) dimensional changes from material changes affecting the OD of catheter shaft; 5) change in adhesive required for bonding metal to a polymer; 6) reduce the number of marker bands on the catheter; and 7) change to colorant for shaft for better visualization of marker bands under endoscopic view.

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, therefore, those tests are not being repeated. However, electrical isolation testing has been repeated and passed successfully. Verification testing to support the proposed catheter modification in this submission was performed.

Once catheters were built and packaged, they were subjected to a 2x sterilization. Testing included mechanical and functional performance of the catheter assembly, sterilization assessment, biocompatibility, packaging and accelerated aging testing. Sample size required for each test was guided by the risk index as determined by the DFMEA. Sample size considered both attribute data and variable data. Results of these tests are presented below.

Test Description	Results		Test Description	Results		Test Description	Results
Incoming Inspection	Passed		Marker Band Durability	Passed		Temperatur e Exposure	Passed
Measure Working Length	Passed		Catheter Handle and Insulation Temperature Testing	Passed		Temperatur e Cycling	Passed
Measure Insulation Length	Passed		Leak Testing	Passed		Bend Angle and Radius	Passed
Distal Shaft Profile Dimensions	Passed		Static Burst Testing	Passed		Retroflex Power	Passed
Visual Marker Band	Passed		Catheter Removal Force	Passed		Cooling Power	Passed
Strain Relief	Passed		Catheter Insertion Force	Passed		Biocompatibility	Passed
Handle Insertion and Removal	Passed		Bayonet Tensile Test	Passed		Sterilizatio n adoption	Accepted
Catheter Insertion into Gastroscope	Passed		Time to Frost	Passed			
Accelerated Aging	Supports 6 months		Ship Test	Passed			

Rationale for Substantial Equivalence:

The technological characteristics of the truFreeze System were compared to the predicate device, the truFreeze System (K162695).

The proposed modifications to the catheter shortens the time required to pre-cool the catheter so that frost is achieved on the tissue faster. The process of pre-cooling the catheter occurs prior to initiating the timer, which signifies the initiation of the dosimetry. There are no changes to the amount of cryogenic energy delivered or the flow rate and there are no changes to dosimetry. These changes are intended to

address a user feedback request. The slight dimensional changes resulting from material changes have no impact on compatibility with the same size gastroscope as the predicate catheter. The colorant used to create a white shaft is biocompatible and provides a distinguishing look to improve endoscopic visualization of the marker bands.

The Intended Use/Indications for Use statements are identical to the predicate device. Since the proposed catheter will be used for active venting procedures only, the instructions for use document will not contain information required for passive venting procedures. Additionally, to enhance safety, a precaution statement was added to remind the user that the catheter should not be used for passive venting procedures as well as a reminder to ensure that the correct catheter was being used. Additionally, to enhance safety, the colors on the outer product label changed to help distinguish the Rapid AV spray kit from the predicate spray kits.

The OD measurement unit of the catheter label has changed from a unit of French (FR) to a unit of mm to support current measurement conventions. This is also reflected in the Operator's manual.

Conclusion

Based on the bench data collected for the truFreeze System, no new questions of safety or efficacy are raised. Therefore, the truFreeze System with the Rapid AV Spray Kit should be considered substantially equivalent to the legally marketed predicate, the truFreeze System.