December 7, 2020

CSA Medical, Inc.
Heather Nigro
SVP, Regulatory/Quality/Clinical Affairs
91 Hartwell Ave
Lexington, Massachusetts 02421

Re: K201183
Trade/Device Name: Vortex Radial Spray Catheter
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: November 4, 2020
Received: November 5, 2020

Dear Heather Nigro:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201183

Device Name
truFreeze® System, Vortex™ Radial Spray Catheter

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°C, requiring either active or passive venting during surgical procedures.

Indications for Use, Vortex™ Radial Spray catheter:
The Vortex™ Radial Spray catheter is indicated for use as a cryosurgical tool to ablate benign (e.g., Barrett's Esophagus with high grade and/or low grade dysplasia) in the upper gastrointestinal tract using active venting.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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CSA Medical, Inc.
truFreeze® System
Vortex™ Radial Spray Catheter
Traditional 510(k) Premarket Notification

K201183

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

Date Prepared: December 7, 2020

Submitter's Information:

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FDA Establishment Owner/Operator Number:	3010140265
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Legal Manufacturer:	CSA Medical, Inc. 91 Hartwell Avenue Lexington, MA 02421
Facility Establishment Identification (FEI) Number:	3004534508
Trade/Proprietary Name:	truFreeze® System, Vortex™ Radial Spray Catheter
Common/Usual Name:	Cryosurgical Catheter
Classification Name: **Regulation Number:** **Product Code:** **Device Classification:**	Cryosurgical Unit, Cryogenic Surgical Device 21 CFR 878.4350 GEH Class II
Predicate Device	truFreeze System, K171626

CSA Medical, Inc.
truFreeze® System
Vortex™ Radial Spray Catheter
Traditional 510(k) Premarket Notification

Device Description:

The CSA Medical (CSA) truFreeze® System consists of a truFreeze Console and a truFreeze Spray Catheter Kit. The truFreeze Console is to be used only with a truFreeze Spray Kit. This document specifically applies to the Vortex Radial Spray Kit (20-00360) for use with the truFreeze® System. Vortex Radial delivers liquid nitrogen in a 3-cm long, 360° spray pattern to ablate circumferential, epithelium such as Barrett's Esophagus.

The Vortex Radial Spray Kit (20-00360) consists of one (1) truFreeze Vortex Radial Spray Catheter (20-00187), one (1) 4-inch Suction Canister Connector, and one (1) Patient Tube.

The catheter is connected to the console and transports cryogen from the console to the targeted ablation area. The Suction Cannister Connector and Patient Tube provide the connection from the suction source in the console to the Cryo-Decompression Tube (CDT) at the end of the catheter, to provide active evacuation (suction) of nitrogen gas at the ablation site. The spray head is surrounded by the Mesh that expands to dilate the lumen to a diameter of 20 mm and center the device during the delivery of cryogen spray.

Indications for use:

The Indications for Use statement for the truFreeze® System is:

> 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 Vortex™ Radial Spray catheter is indicated for use as a cryosurgical tool to ablate benign lesions (e.g., Barrett's Esophagus with high grade and/or low grade dysplasia) in the upper gastrointestinal tract using active venting.

Technological Characteristics:

The proposed device and predicate device are based on the same technological characteristics including principle of operation via pressure-propelled cryogen, application of liquid nitrogen to ablate unwanted tissue, and delivery of equivalent cooling power density per unit area. The differentiator for the Vortex™ catheter is that the cryogen is sprayed radially as compared to the previously cleared catheters which spray linearly.

Characteristic	Predicate truFreeze® System, (171626)	Proposed truFreeze® System, Vortex™ Radial Spray Kit
Intended Use	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.	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.

CSA Medical, Inc.
truFreeze® System
Vortex™ Radial Spray Catheter
Traditional 510(k) Premarket Notification

Indication 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 (eg. Barrett's Esophagus with high grade and/or low grade dysplasia) and malignant lesions.	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 Vortex™ Radial Spray catheter is indicated for use as a cryosurgical tool to ablate benign lesions (e.g., Barrett's Esophagus with high grade and/or low grade dysplasia) in the upper gastrointestinal tract
Cryogen	Liquid nitrogen	Liquid nitrogen
Principle of Operation	Pressure Propelled Cryogen	Pressure Propelled Cryogen
Mode of Ablation	≥1 freeze-thaw cycles, Quantity determined by physician	≥1 freeze-thaw cycles, Quantity determined by physician
Delivery/Cryoprobe	Spray Tip (Linear)	Spray Tip (Circumferential)
Output Temperature	-196°C	-196°C
Cooling Power Density, Low Flow (12.5 W, N/A W)	2.7 to 4.0 W/cm^2	N/A
Cooling Power Density, Normal Flow (25 W, 100 W)	5.3 to 8.0 W/cm^2	5.3 W/cm^2
[1]Depth of Freeze in Hydrogel when used per IFU at nominal settings (mean ± SD)	1.0 mm ± 0.4 mm	1.0 mm ± 0.2 mm
Delivery of Cryogen (spray dosimetry)	Physician-controlled duration (GUI activated timer with audible cues) 0 s to 60 s, 5-s increment	Physician-controlled duration (pedal activated timer with audible cues) 10 s to 20 s, 1-s increment
Procedure Visualization	Direct visualization via endoscope	Direct visualization via endoscope
Early spray termination	User control via foot pedal release or emergency stop button	User control via foot pedal release or emergency stop button
Prevent use/reuse of expired or invalid catheter	Confirms use of valid catheter using RFID	Confirms use of valid catheter using RFID
Notifies physician to stop spraying	Audible beeper to coincide with visual display of timer	Audible beeper to coincide with visual display of timer. Console terminates spray at physician-selected duration

Computerized test of system prior to use	Software test confirms system is properly operating before exposure of cryotherapy	Software test confirms system is properly operating before exposure of cryotherapy
Computerized continuous monitoring of system during procedures	Uses computer program to abort freezing if a system failure is detected	Uses computer program to abort freezing if a system failure is detected
Ensure patient is not exposed to high pressure gases	Uses active suction pump and CDT (active), or a natural orifice (passive), as per instructions for use. IFU provides venting guidance for proper gas egress.	Uses active suction pump and integral CDT (active) and passive egress channels as per instructions for use. Console pump activation during spray delivery. IFU provides venting guidance for proper gas egress.
Protect healthy tissue from excessive temperatures	Provides sufficient insulation to maintain safe temperature on patient and user exposure surfaces	Provides sufficient insulation to maintain safe temperature on patient and user exposure surfaces
Pressure Controls	Valves and pressure transducer to control pressure of liquid nitrogen; redundant pressure switch; mechanical relief valve; redundant burst disc.	Valves and pressure transducer to control pressure of liquid nitrogen; redundant pressure switch; mechanical relief valve; redundant burst disc.
Thermal/Defrost	Active defrost capability to thaw catheter using warm nitrogen gas	Active defrost capability to thaw catheter using warm nitrogen gas
Safe Storage of Cryogen	Internal Pressure-rated vacuum insulated Dewar	Internal Pressure-rated vacuum insulated Dewar
Product Label	Uniquely identifies catheter as linear spray for active or passive venting procedures.	Uniquely identifies catheter as radial spray for active venting procedures.
Sterility	Sterile catheter provided using Ethylene Oxide with SAL 10^{-6}	Sterile catheter provided using Ethylene Oxide with SAL 10^{-6}
Biocompatibility	Patient (direct and indirect) contacting materials comply with ISO 10993	Patient (direct and indirect) contacting materials comply with ISO 10993

Summary of Performance Testing – Bench, Non-clinical, Clinical:

A number of bench tests were conducted to verify the product design met the predetermined product performance specifications. Testing was inclusive of the following: Product Design and Software verification, Shelf-life in accordance with ISO 11607, Sterilization in accordance with ISO 11135:2014, EMC/Safety per IEC 60601-12:2014, Distribution Testing per ISTA 2A:2011 and Usability. The Vortex™ Radial Spray catheter is classified as surface contacting, mucosal membrane device having limited contact duration (<24 hours) therefore requiring cytotoxicity,

sensitization and irritation testing. This testing was conducted in accordance with ISO 10993-1:2018, including 10993:5 and 10993:10. All testing confirmed that the product specifications had been met, demonstrated that the device is adequately designed for the labeled indications for use and the risk management report concluded that the benefits of the device outweigh the associated risks.

Three preclinical GLP studies were completed utilizing the Vortex™ Radial Spray catheter in swine for the purposes of dose ranging and gathering evidence of procedural safety consistent with other cleared truFreeze® accessories. Histopathology data confirmed a 3-cm-long circumferential treatment zone and showed controlled depth of injury without reaching the serosa. All animals survived and no serious adverse events were reported.

Three scientific, peer-reviewed literature articles have been published demonstrating the ability of the predicate device (i.e. linear spray) to achieve circumferential freezing of diseased tissue in the esophagus. The scientific, peer-reviewed literature provided evidence that 73 patients have been treated with spray LN2 circumferentially since 2012 to ablate BE lesions with a safety and efficacy profile. Additionally, Real-World Data (RWD) has been extracted from an ongoing prospective, multi-center patient registry which further documents evidence of circumferential spray of LN2 with a safety profile. Of the 112 patients identified in the registry as having Barrett's Esophagus, 49 of those patients received circumferential ablation. The mean BE segment length from the first procedure was 4.8 cm (range 1.0 – 13.0 cm) and the mean number of circumferentially ablated segments per procedure was 2.64 (range 2.0 - 7.0). The dosimetry used was consistent with the IFU for the linear spray catheter as most patients were treated with two sprays for 20 seconds. Procedures associated with an adverse event, stricture or serious adverse event are all below 4%.

Comparison to Predicate:

The truFreeze® Vortex™ catheter has the same intended use and utilizes the same fundamental technology as the predicate truFreeze® System and catheters (K171626). The truFreeze® Vortex™ catheter has been compared to the legally marketed predicate device as cleared through K171626 (August 30, 2017) and there are no new safety or effectiveness questions raised with this proposed modification. Therefore, it is believed that the proposed Vortex™ Radial Spray catheter is substantially equivalent to the truFreeze® System described in K171626.