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

August 30, 2017

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

Re: K171626
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: June 2, 2017
Received: June 2, 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 (DICE) 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 (DICE) 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)*
K171626

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 (e.g. Barrett's Esophagus with high grade dysplasia and/or low 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.

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

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510K SUMMARY

Applicant	CSA Medical, Inc.
Establishment Registration Number	3010140265
Contact Person	SherrieCoval-Goldsmith,M.S. Vice PresidentRA/QA CSA Medical 91 Hartwell Ave Lexington, Ma 02421 Phone:781-538-7447 Fax:781-538-4730 sgoldsmith@csamedical.com
Summary Date	June 2, 2017
Proprietary Name	truFreeze® System
Classification	Class II
Classification Name	Cryosurgical Unit, Cryogenic Surgical Device
Regulation Number	21 CFR878.4350
Classification Product Code	GEH
Predicate Device	K163244(truFreeze®System)
Reference Devices	K152329(Coldplay CryoBalloon™ FocalAblation System), K083737 (Barrx System), and K 161202 ((Coldplay CryoBalloon™ FocalAblation 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. The console is the same as

previously cleared for the predicate truFreeze System (K163244). Therefore, there are no new issues of safety or effectiveness raised.

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 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. The disposable kit is the same as previously cleared for the predicate truFreeze System (163244). Therefore, there are no new issues of safety or effectiveness raised.

LABELING (INTENDED USE/INDICATIONS FOR USE AND INSTRUCTIONS FOR USE DOCUMENT)

The Intended Use/Indications for Use statement is identical in its Intended Use as the predicate device with the exception of adding a specific indication for use as an example of benign tissue that can be ablated with truFreeze. Clinical data have been generated to substantiate a change in label claim. The proposed modification adds Barrett's Esophagus with low grade dysplasia into the Indications for Use statement as an example of benign tissue to be ablated.

PROPOSED INTENDED USE/INDICATIONS FOR USE

The truFreeze System is intended for cryogenic destruction of tissue using Liquid Nitrogen spray that has a boiling point of -196^{o}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 (eg. Barrett's Esophagus with high grade and/or low grade dysplasia) and malignant lesions.

TECHNICAL AND OPERATIONAL CHARACTERISTICS

The truFreeze System is identical in design, operational and technological characteristics as the predicate device and supports that no new safety concerns are being raised by changes in the 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. Data was previously submitted to support that the use of liquid nitrogen is cold enough to ablate benign or malignant lesions (K133258) and reference is being made to that data. Clinical data are summarized below.

Previous, clinical data was generated to support the addition of BE-HGD (K163244) to the indications for use. In a post-market registry study, 46 patients with Barrett's Esophagus high grade dysplasia received ablation with the truFreeze device. Patients received an average of 1.89 ablations sessions consisting of an average of 2.23 cycles of 21.17seconds to achieve CE-D in 87% of the patients. Details are presented in the tables 1-2 below.

Table 1 BE-HGD Effectiveness Data

	Response CE-D
Efficacy Population	46
N Responders	40 (87.0%)
Response rate by BE segment length	
Unknown	2 (4.3%)
≤ 3 cm	27 (58.7%)
3-6 cm	7 (15.2%)

Table 2 BE-HGD Safety Data

Safety	truFreeze Per Patient rate
Stricture	2.7%
Abdominal Pain	0%
Pancreatitis	0.9%
Chest pain	0%
GI Hemorrhage	0%
Mucosal Lacerations	0%

RATIONALE FOR SUBSTANTIAL EQUIVALENCE

The Intended Use/Indications for Use statement and technological characteristics of the truFreeze System and the predicate device were compared. The Intended Use/Indications for Use statement of the two devices had equivalent general claims except that BE-HGD (as an example of a specific benign lesion that can be ablated) was added to the indications for use statement.

Clinical data are presented to support the safety and effectiveness of adding Barrett's Esophagus with low grade dysplasia as an example of specific benign tissue that can be ablated.

A clinical summary of data collected from a post market registry study (ClinicalTrials.gov Identifier: NCT01802203) supports this submission. This post-marketing registry prospectively collected data on patients treated with the FDA-cleared cryotherapy device (truFreeze® System). The instructions for use document guided the dosimetry used for ablation procedures.

Similar to any clinical trial, physicians offered "all comers" with BE to participate in the registry if they met all inclusion criteria and none of the exclusion criteria. Patients were sequentially and consecutively enrolled into the registry at participating trial.

The registry had pre-defined inclusion / exclusion criteria, which are consistent with the instructions for use of the cleared device. CSA Medical applied 3 additional exclusion criteria that were sequentially applied to the population of BE patients. These exclusion criteria included items 3-5 in Table 3 below.

This yielded patients for the effectiveness population.

Two medical societies cite endoscopic radiofrequency ablation (RFA) as a recognized ablation method for BE LGD.[1,2] A rate of 90.5% CE-D is cited in the literature.[1]

The clinical data for the patients with Barrett's Esophagus low grade dysplasia are provided in Tables 3- 9 below.

Table 3 Summary of Populations analyzed

Inclusion Criteria	1. Able to read, comprehend, and complete the informed consent form. 2. Aged 18 or older. 3. Receiving spray cryotherapy procedure with the truFreeze device for the first time for removal of unwanted tissues including malignant or pre- malignant conditions of the aerodigestive system.
Exclusion Criteria	1. Contraindication to spray cryotherapy. 2. Prior treatment with spray cryotherapy. Previous or concurrent treatment using other mucosal therapies such as endoscopic mucosal resection or radiofrequency ablation is acceptable. 3. Patients not having Barrett's Esophagus with low grade dysplasia. 4. Patients without a pre-therapy and post-therapy histology. 5. Patients who received other therapies (such as endoscopic mucosal resection) during the ablation therapyperiod.
Safety Population/Effectiveness	111 Patients 22 patients
Device Used	truFreeze System

Table 4 Demographics

	BE Patients (Safety Population) (N=111)	BE LGD Patients (Effectiveness Population) (N=22)
Age (years)		
n	111	22
Mean (SD)	67.8 (10.8)	69.2 (7.84)
Range	24 - 89	51 - 83
Gender, no. (%)		
Female	29 (26.1%)	5 (22.7%)
Male	82 (73.9%)	17 (77.3%)
Segment length (cm)		
<= 3	65 (59%)	9 (41%)
3-6	17 (15%)	3 (14%)
>=6	21 (19%)	8 (36%)
Unknown	8 (7%)	2 (9%)
Endoscopic mucosal resection		
Previous EMR, no. (%)	30 (28%) (N=109)	2 (10%) (N=21)
Mean time since EMR(months), mean (SD)	6.9 (11.8)	4.5 (5.1)

Table 5. Procedure Information to Achieve Best Response

	22 BE-LGD Patients in Effectiveness Population
Patients receiving 1 procedure session to best response	10 (45%)
Patients receiving 2 procedure sessions to best response	5 (23%)
Patients receiving 3 procedure sessions to best response	5 (23%)
Patients receiving >3 procedure sessions to best response	2 (9%)
Mean Procedure Sessions (SD)	2 (1.1)
Mean Cycles per procedure (SD)	2.19 (0.72)
Mean Time (sec) per cycle (SD) (seconds)	21.76 (3.67)

Table 6 Procedure or Device Related Adverse Event Rate per Procedure Session

	BE Patients Safety Population Procedures (258 procedures)	BE LGD Patients Effectiveness Population Procedures (52 procedures)
Stricture	3 (1.2%)	0 (0%)
Pancreatitis*	1 (0.4%)	0 (0%)

***** This is the only serious adverse event reported. The physician stated the relationship of truFreeze treatment and development of pancreatitis was highly unlikely. However, a possible causal relation with the device could not be ruled out because of the temporal association.

Table 7 Barrett's segment length for CE-D Results

	Response CE-D
Effectiveness Population	22
N Responders	21 (95.5%)
Response rate by BE segment length	
Unknown	2 (10%)
<= 3cm	9 (43%)
3-6cm	3 (14%)
>=6cm	7 (33%)

Table 8 Safety Data

	truFreeze Per Patient Rate Safety Population (N=111)
Stricture	3 (2.7%)
Abdominal Pain	0 (0%)
Pancreatitis	1 (0.9%)
Chest Pain	0 (0%)
GI Hemorrhage	0 (0%)
Mucosal Lacerations	0 (0%)

Table 9 Effectiveness Data

	CE-D Patients (N=22)
truFreeze	21 (95.5%)

Additionally, 3 peer reviewed articles support the effectiveness of the truFreeze System to ablate BE-LGD and are presented in table 10.

Table 10 Summary of articles/presentations

Reference No.	No. of BE LGD patients treated	No Achieving CE-D	No Achieving CEIM	Comments
3	23	21		
4	4	3		
5	13	Not reported	13	Note: achieving CEIM is a more difficult endpoint to achieve vs CE-D
Total	40	24	13	93 % of patients achieved CE-D

DISCUSSION

The data show that the majority of BE-LGD patients were successfully treated with the truFreeze device. Among the 22 BE-LGD patients in the effectiveness population, 21 (95.5 %) achieved a response of CE-D. Additionally, among 40 BE-LGD patients presented from peer reviewed literature, 37 (93%) were successfully treated with the truFreeze device.

This success rates are comparable to the success rate among the LGD phenotype of BE patients for the Barrx System and the Coldplay CryoBalloon™ Focal Ablation System.

The safety rate of the trufreeze device is also substantially equivalent to these reference devices.

CONCLUSION

In summary, endoscopic ablation of Barrett's Esophagus with low grade dysplasia with the truFreeze device does not raise new questions of safety or effectiveness as compared to the reference devices or the predicate device and warrant adding Barrett's Esophagus with low grade dysplasia as an example of benign tissues that can be ablated, to the truFreeze label.

References

1. ASGE Standards of Practice Committee. The role of endoscopy in Barrett's esophagus and other premalignant conditions of the esophagus. Gastrointestinal Endoscopy 2012; 76 (6): 1087 (available at https://www.asge.org/docs/default-source/education/practice_guidelines/doc-the- role-of-endoscopy-in-barretts- esophagus-and-other-premalignant-conditions-of-the- esophagus.pdf?sfvrsn=8).

2. Nicholas J. Shaheen , MD, MPH, FACG , Gary W. Falk , MD, MS, FACG, Prasad G. Iyer , MD, MSc, FACG andLauren Gerson , MD, MSc, FACG. ACG Clinical Guideline: Diagnosis and Management of Barrett's Esophagus. Am J Gastroenterol advance online publication, 3 November 2015; doi: 10.1038/ajg.2015.322 (available at https://gi.org/guideline/diagnosis-and-management-of-barretts-esophagus/)

3. Ghorbani S, et al. "Safety and efficacy of endoscopic spray cryotherapy for Barrett's dysplasia: results of the National Cryospray Registry." Diseases of the Esophagus. 2015: 29: p241–247. doi:10.1111/dote.12330. http://onlinelibrary.wiley.com/doi/10.1111/dote.12330/abstract;jsessionid=6FECC3D65017B2C6003584B066D31F5E.f01t04

4. Barthel JS, et al. "Cryoablation of persistent Barrett's epithelium after definitive chemoradiation therapy for esophageal adenocarcinoma." Gastrointestinal Endoscopy. 2011: Volume 74, Issue 1, p.51-57. http://www.giejournal.org/article/S0016-5107%2811%2901343-5/abstract

5. Eluri S, et al. “Liquid Nitrogen Spray Cryotherapy Effectively Eradicates Barrett’s Esophagus irrespective of Severity of Baseline Histology: Results of a US multicenter Registry. Gastrointestinal Endoscopy. 2017 : Volume 85 No 5S.