510K Summary
TruFreeze® System

Applicant: CSA Medical
Establishment Registration Number: 3004534508
Contact Person: Sherrie Coval-Goldsmith

Summary Date: June 9, 2014
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: K102360 IceSense3

Device Description

The truFreeze system is a cryosurgical tool that applies medical-grade liquid nitrogen to the treatment area via a small, low pressure, open tipped catheter. The truFreeze System consists of (1) a console and (2) 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 wireless remote control provides alternative timer control from a distance in the treatment room. 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:
The truFreeze disposable spray kit consists of 5 individually packaged sterile single-use catheters (7 Fr Straight Tip Catheter and one Catheter Introducer.) and 5 individually packaged cryogen decompression tubes (CDTs) (each containing one Dual Lumen 20 Fr CryoDecompression Tube (CDT), Connector, and Suction Tubing.). The catheter is flexible and capable of retroflex in a scope. The CDT and accessory tubes are included for use with the on-board suction system.

Intended Use/Indications for Use

The truFreeze System is similar in its Intended Use as the predicate device (K102360 IceSense3). Both devices describe the ablation of benign and malignant tissue in general terms.

The requirement to use active or passive venting is in the cleared truFreeze Instructions for Use document (K113021) and adding it to the intended use/indications for use statement highlights the importance of venting and will enhance safe use of the device. Therefore, the revised intended use/indications for use statement raises no new issues of safety or effectiveness.

The truFreeze is intended for cryogenic destruction of tissue requiring either active or passive venting during surgical procedures.

The truFreeze is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign and malignant lesions.

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, limited bench testing was conducted to support.
demonstration of substantial equivalence in performance from the truFreeze to its predicate device. A summary table of the bench testing is provided below:

<table>
<thead>
<tr>
<th>Bench Test Characteristic</th>
<th>Proposed truFreeze System (K133258)</th>
<th>Predicate IceSense3 (K102360)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to reach equivalent dose (using same freeze/thaw/freeze cycle)</td>
<td>2min/2min/2min = 1.8-2.4cm 3min/2min/3min = 2.4-3.0cm 4min/4min/4min = 3.0-3.6cm</td>
<td>2min/2min/2min = 2.1-2.5cm 3min/2min/3min = 2.6-3.0cm 4min/4min/4min = 3.1-4.0 cm</td>
<td>Both capable of producing equivalent depth of ice</td>
</tr>
<tr>
<td>Output Temperature at tip</td>
<td>-196 degree C</td>
<td>-170 degree C</td>
<td>Both achieve temperatures low enough to destroy malignant tissue</td>
</tr>
<tr>
<td>Equivalent temperature distribution using the radial distance from the 0°C isotherm (border of ice ball) to the -20°C, -40°C and -50°C isotherms</td>
<td>@ freeze depth of 21.87 mm at 0°C -20°C isotherm at 15.5 mm depth -40°C isotherm at 11.8 mm depth</td>
<td>@ freeze depth of 22 mm at 0°C -20°C isotherm at 16.9 mm depth -40°C isotherm at 13.4 mm depth</td>
<td>Both can produce lethal ice at comparable depths</td>
</tr>
</tbody>
</table>

**Rationale For Substantial Equivalence**

The Intended Use/indications for Use statement and technological characteristics of the truFreeze System and the predicate device (K102360 IceSense3) 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. Bench testing demonstrated that both devices can achieve equivalently cold temperatures in equivalent time periods to produce equivalent amounts of ice. These temperatures are cold enough to destroy unwanted benign or malignant tissue. This proposed change to the indications for Use 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 benign or malignant tissue during surgical procedures.

The truFreeze device requires either active or passive venting for safe use. This is described within the previously cleared Instructions for Use document for the truFreeze device. The addition of this statement to the Intended Use/indications for Use statement enhances the safe use of the device.

**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.
June 19, 2014

Ms. Sherrie Coval-Goldsmith
Vice President, Regulatory Affairs/Quality Assurance
91 Hartwell Avenue
Lexington, Massachusetts 02142

Re: K133258
Trade/Device Name: truFreeze\textsuperscript{TM} System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 15, 2014
Received: May 16, 2014

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/Industrv/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/Industrv/default.htm.

Sincerely yours,

David Krause

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
Indications for Use

The truFreeze is intended for cryogenic destruction of tissue requiring either active or passive venting during surgical procedures.

The truFreeze 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)

- ✔ Prescription Use (Part 21 CFR 801 Subpart D)
- ❏ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

For FDA Use Only:

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joshua C. Nipper -S

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

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Papework Reduction Act (PRA) Staff
PRAS staff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*