DEC 7 2007

510(k) Safety Summary

September 2007
Submitted by:

CSA Medical, Inc.
Emerging Technology Center
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Contact Person: Jennifer Cartledge, VP Development, CSA Medical, Inc.
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Name of Device

- Trade Name: CryoSpray Ablation System
- Common Name: Cryosurgical Unit, Cryogenic Surgical Device
- Classification: Cryosurgical unit with Liquid Nitrogen, Class II [21 CFR § 878.4350(a)].
- Establishment Registration Number: 9062377

Predicate Devices

Device	Premarket Notification
SprayGenix™ Cryo Ablation System	K060555
CryoSpray Ablation System	K070893
CryMed Cryo-Ablator	K040809

Company History:

CSA Medical, Inc., formerly CryMed Technologies, Inc., received market clearance for the SprayGenix™ Cryo Ablation System (K060555). The name for the SprayGenix™ Cryo Ablation System was changed to the CryoSpray Ablation™ System as documented in the letter to file dated March 12, 2007.

Device Modification Description:

The CryoSpray Ablation™ System is used to destroy unwanted tissue by application of extreme cold to a selected site. Liquid Nitrogen is stored in a tank and then propelled through a cryo-catheter to perform the cryo-ablation procedure. The catheter, an accessory component of the CSA System, is placed in the

appropriate position through the use of visual observation. The cryo-catheter applies the cryogen to a selected area and freezes the unwanted tissue. The Nasal/Oral Gastric Tube detailed in the K060555 and K070893 submission is of a single lumen design, with suction ports spanning the distal 15 inches of the tube, allowing ports to be positioned in the esophagus and stomach simultaneously.

The only device modification presented in this Abbreviated 510(k) submission involves a tubing configuration modification for the Nasal/Oral Gastric Tube. The modified Nasal/Oral Gastric Tube is a dual lumen product with the addition of a vent lumen for the gastric section of the tube. While identical materials are used as compared to the Nasal/Oral Gastric Tube listed in submission K060555 and K070893, the dual lumen tubing allows one lumen to provide active suction while the second lumen provides passive venting in the gastric section. Refer to Attachments A.

Indications for Use:

The CryoSpray Ablation™ System is intended to be used as a cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

The intended use of the Nasal/Oral Gastric Tube, as described in its labeling, has not changed as a result of the configuration modification. Refer to Attachment C.

Technical Characteristics:

The modification to the Nasal/Oral Gastric Tube does not change the operating principals or mechanism of action for the CryoSpray Ablation System and it is substantially equivalent to the above listed predicate devices.

Summary:

Based on the principles of operation, design, materials and intended use, the modification to the Nasal/Oral Gastric Tube results in a CryoSpray Ablation™ System that is substantially equivalent to devices currently marketed in the United States.

Certification of Conformance Standard:

Refer to Attachment 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CSA Medical, Inc.
% Mr. Tim Askew
President & CEO
1101 E. 33rd Street, #E305
Baltimore, Maryland 21218

DEC - 7 2007

Re: K072651
Trade/Device Name: CryoSpray Ablation™ System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: November 8, 2007
Received: November 20, 2007

Dear Mr. Askew:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

DEVICE NAME: CryoSpray Ablation™ System CSA Medical, Inc.

INDICATIONS FOR USE:
The CryoSpray Ablation™ System is intended to be used as a cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_____ or Over-The-Counter Use_____
(per 21 CFR 801.109

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072651