APR 2 1 2006

510(k) Safety Summary

K060555

February 2006
Submitted by:

CryMed Technologies, Inc.
CryMed Technologies, Inc.
Emerging Technology Center
3225 Ellerslie Ave., Third Floor - #B311
Baltimore, MD 21218
O: 443.921.8053
Contact Person: Tim Askew, President CryMed Technologies, Inc.

Name of Device

- Trade Name: SprayGenix™ Cryo 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
CryMed Cryo-Ablator	K040809
Wallach Surgical Devices WA1000	K813024
Figitronics Cryo-Plus ™	K811390
Figitronics Cryo-Surg™System 5900	K840536
Wallach Surgical Devices UltraFreeze	K935010
Cortex Technology's Cryopro Maxi and Cryopro Mini	K982280
CMS Cryolite	K970995

Device Description

The SprayGenix™ Cryo Ablation System is a cryosurgical device, consisting of an electronic console, cryo-catheter, nasal/oral gastric tube and cryogen delivery system.

The SprayGenix™ Cryo 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 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. Cryosurgical procedures are

used when surgical resection is not indicated, and may also provide an alternative to typical resection in certain cases.

Indications for Use

The SprayGenix™ Cryo 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.

Technical Characteristics

The technology used by CryMed Technologies, Inc. is substantially equivalent to those of the above listed predicate devices.

Summary

Based on the principles of operation, design, materials and intended use, the SprayGenix™ Cryo Ablation System is substantially equilivant to devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2006

CryMed Technologies, Inc.
c/o Mr. Tim Askew
President
Emerging Technology Center
3225 Ellerslie Avenue
Third Floor - #B311
Baltimore, Maryland 21218

Re: K060555
Trade/Device Name: SprayGenix™ Cryo Ablation
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: February 24, 2006
Received: March 2, 2006

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): ___ K060555

DEVICE NAME: SprayGenix™ Cryo Ablation CryMed Technologies, Inc.

INDICATIONS FOR USE:
The SprayGenix™ Cryo 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescrition 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 K060555