MAY 21 2004

K040809

**510(k) Safety Summary**

March 22, 2004
Submitted by:

CryMed Technologies, Inc.
319 W. Timonium Road
Lutherville, MD 21093
Tel. 410-252-3313
Fax 410-252-9489
Contact Person: Frank Majerowicz, President CryMed Technologies, Inc.

Name of Device

- Trade Name: CryMed Cryo-Ablator
- Common Name: Cryosurgical Unit, Cryogenic Surgical Device
- Classification: Cryosurgical unit with Liquid Nitrogen, Class II [21 CFR § 878.4350(a)].
- Establishment Registration Number: Applied for on 3/20/04

Predicate Devices

| Device | Premarket Notification |
|---|---|
| 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 Cryo-Ablator System is a cryosurgical device, consisting of an electronic console, cryo-catheter and cryogen tank.

The Cryo-Ablator 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 CryMed Cryo-Ablator System is similar in form and function to the Cryomedical Sciences' CMS Cryolite, Wallach Surgical Devices WA1000 (K813024) and its UltraFreeze (K935010), Figitronics' Cryo-Plus ™ (K811390) and its Cryo-Surg™System 5900 (K840536), and the Cortex Technology's Cryopro Maxi and Cryopro Mini (K982280). The intended use for the CryMed Cryo-Ablator System is the same as those listed for the CryMed Cryo-Ablator System predicate devices.

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 CryMed Cryo-Ablator 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

MAY 21 2004

Mr. Frank Majerowicz
President
CryMed Technologies, Inc.
319 W. Timonium Road
Lutherville, Maryland 21093

Re: K040809
Trade/Device Name: CryMed Cryo-Ablator
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: March 22, 2004
Received: March 29, 2004

Dear Mr. Majerowicz:

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 (301) 594-4659. 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,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
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): K040809

Device Name: CryMed Cryo-Ablator from CryMed Technologies, Inc.

Indications For Use:

The CryMed Cryo-Ablator System is intended to be used as a cryosurgical tool for destruction of unwanted tissue in the fields of dermatology, gynecology and general surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

**510(k) Number** K040809