K973190

NOV 21 1997

# 510(k) SUMMARY

August 19, 1997

**Submitted by:**

Cryomedical Sciences, Inc.
1300 Piccard Drive
Suite L105
Rockville, Maryland 20850
(301) 417-7070
Fax (310) 417-7077

**Contact:**

Richard J. Reinhart, Ph.D.
President and CEO
or
Susan Hayes
Regulatory Affairs

**Proprietary name:** CMS AccuProbe® Models 450, 550/530 and 600 Series

**Common name:** Cryosurgical Units, Cryogenic Surgical Device

**Classification:** Cryosurgical units with Liquid Nitrogen, Class II [21 CFR § 878.4350(a).

The sole purpose of this submission is to augment the labeling and advertisements which describe intended use of the CMS AccuProbe device family, the AccuProbe® 450, the AccuProbe® 550/530 and the AccuProbe® 600 Series.

The company believes that its CMS AccuProbe® device's original predicate devices and other legally marketed cryosurgical devices, listed below, are substantially equivalent for intended use and advertisement.

# CMS Cryosurgical Device Family Comparison With Other Cryosurgical Devices

| Cryosurgical Device | Type of System | Cryogen Used |
|---|---|---|
| CMS AccuProbe® Systems | Console with multiple ports and spray/closed probes | Liquid nitrogen |
| Frigitronics Model Zacarian C-21and Cryo-Surg | Hand-held body with spray probes only for C-21 and spray and closed probes for the Cryo-Surg | Liquid nitrogen |
| Frigitronics Models CM-73 and CT -82 | Hand-held body and closed probes | Nitrous oxide |
| Frigitronics Model CE-4G* | Console with single port and closed probes | Liquid nitrogen |
| Frigitronics Models CS-76 and CE-8 | Console with single port and closed and spray probes | Liquid nitrogen |
| ERBE Erbokryo* | Console and single probe | Liquid nitrogen |
| Candela Cryotech Models LCS 2000 and 3000 | Console with multiple ports and spray and closed probes | Liquid nitrogen |
| Brymill Corporation Kryospray | Hand-held spray | Liquid nitrogen |
| Physicians Products, Inc. | Spray container | Liquid nitrogen |
| Spembly Medical 130 Cryounit | Console with single port and spray and closed probes | Liquid nitrogen |
| Cabot Medical's Models MT-700, MT750, FT-350 and MC-8000 | Hand-held system with single probe port | Nitrous oxide with choice of $N_2O$ and $CO_2$ in Model MT750 |

*Original predicate device to the CMS AccuProbe® device family

The following is the purposed intended use statements with predicate device citations noted:

**Urology**

- *The* ***(A)*** *system may be used to ablate prostatic tissue.*
- *The* ***(A)*** *system may be used for the ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia.*

**(Candela/Cryotech LCS 3000 at Tab F)**

**(ERBE Erbokryo models NL, PS, PSC(T) and PSC Super at Tab E*)**

**(Candela Press Release dated April 8, 1996 at Tab F)**

**Oncology**

- *The (A) system may be used for ablation of cancerous or malignant tissue.*
- *The (A) system may be used for ablation of benign tumors.*
- *The (A) system may be used for palliative intervention.*

**(Candela/Cryotech LCS 3000 at Tab F)**

**(Spembly Medical 130 Cryounit at Tab I)**

**Dermatology**

- *The (A) system may be used for the ablation or freezing of skin cancers and other cutaneous disorders.*

**(ERBE Erbokryo models NL, PS, PSC(T) and PSC Super at Tab E*)**

**(Frigitronics Cryo-Surg at Tab J )**

**(Spembly Medical 130 Cryounit at Tab I)**

**Gynecology**

- *The* ***(A)*** *system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.*

**(ERBE Erbokryo models NL, PS, PSC(T) and PSC Super at Tab E*)**

**General Surgery**

- *The* ***(A)*** *system may be used for the ablation of leukoplakia of mouth, angiomas, sebaceous hyperpalsia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, peri-anal condylomata, pilonidal cysts, actinic and seborrheic keratoses , cavernous hemangiomas, recurrent cancerous lesions.*
- *The* ***(A)*** *system may be used for the destruction of warts or lesions.*
- *The* ***(A)*** *system may be used for the palliation of tumors of the oral cavity, rectum, breast, and skin.*

**(Brymil Corporation at Tab H)**

**Thoracic Surgery**

- *The* ***(A)*** *system may be used for the ablation of arrhythmic cardiac tissue.*

**(Cooper Surgical Cardiovascular cryosurgical system CCS-1— at Tab L)**

**Proctology**

- *The* ***(A)*** *system may be used for the ablation of benign or malignant growths of the anus and rectum*
- *The* ***(A)*** *systems may be used for the ablation of hemorrhoids.*

**(ERBE Erbokryo m models NL, PS, PSC(T) and PSC Super at Tab E*)**

**(Frigitronics/CooperVision Systems at Tab J)**

* Original predicate of CMS AccuProbe device family.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard J. Reinhart, Ph.D.
President and CEO
Cryomedical Sciences, Incorporated
1300 Piccard Drive, Suite L105
Rockville, Maryland 20850

NOV 21 1997

Re: K973190
Trade Name: AccuProbe® 450, AccuProbe® 550/530 and The AccuProbe® 600 Series
Regulatory Class: II
Product Code: GEI
Dated: August 19, 1997
Received: August 25, 1997

Dear Dr. Reinhart:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the devices, 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 be advised that this substantial equivalence determination does not include an indication for cryoablation of the endometrium. The use of cryosurgery for endometrial ablation raises new types of safety and effectiveness questions when compared to currently identified predicate devices used for this purpose and therefore will require submission of a premarket approval application (PMA) to market for this indication.

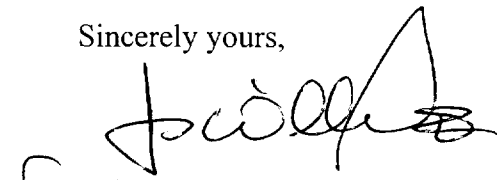
Since, no data has been developed to establish the safety and effectiveness of this cryosurgical device for endometrial ablation, you may not market or promote such use until you have submitted such data and received clearance or approval for this claim.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

Each proposed intended use description will have the letter **(A )** which represents any of the family of AccuProbe® devices, the AccuProbe® 450, AccuProbe® 550/530 and the AccuProbe® 600 Series inclusive.

**Urology**

- The **(A)** system may be used to ablate prostatic tissue.
- The **(A)** system may be used for the ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia.

**Oncology**

- The **(A)** system may be used for ablation of cancerous or malignant tissue.
- The **(A)** system may be used for ablation of benign tumors.
- The **(A)** system may be used for palliative intervention.

**Dermatology**

- The **(A)** system may be used for the ablation or freezing of skin cancers and other cutaneous disorders.

**Gynecology**

- The **(A)** system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973190

# Indications for Use

(continued for CMS AccuProbe® device family)

**General Surgery**

- The **(A)** system may be used for the ablation of leukoplakia of mouth, angiomas, sebaceous hyperpalsia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, peri-anal condylomata, pilonidal cysts, actinic and seborrheic keratoses , cavernous hemangiomas, recurrent cancerous lesions.
- The **(A)** system may be used for the destruction of warts or lesions.
- The **(A)** system may be used for the palliation of tumors of the oral cavity, rectum, breast, and skin.

**Thoracic Surgery**

- The **(A)** system may be used for the ablation of arrhythmic cardiac tissue.
- The **(A)** system may be used for the ablation of cancerous lesions.

**Proctology**

- The **(A)** system may be used for the ablation of benign or malignant growths of the anus and rectum
- The **(A)** systems may be used for the ablation of hemorrhoids.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K973190