SEP 8 1998

K982055

510(k) SUMMARY

June 11, 1998

Submitted by:

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Contact:

Richard J. Reinhart, Ph.D.
President and CEO

Proprietary name: CMS AccuProbe®
Models 810, 820, 830, 840, 850, 860, 870, and 880

Common name: Cryosurgical units and accessories

Classification: Cryosurgical units with Liquid Nitrogen, Nitrous Oxide, Carbon Dioxide, Class II, under CFR § 878.4350. Under CFR § 882.4250 a cryogenic surgical device also is classified in Class II.

The CMS AccuProbe® 800 Series consists of eight models, each of which has two components: i) a console with a pumping mechanism to compress and pressurize the cryogen and ii) one to eight (models 810 through 880) cryoprobes with tips extending from the console. The may include an **optional** on-board computer which is as redundant display system and archival system to store information about the procedure. The computer does not control or affect the operation of the cryoprobes in any fashion. The cryoprobes consist of interchangeable tips of various materials, sizes and shapes which are used a necessary.

The AccuProbe® 800 Series is used to destroy unwanted tissue by the application of extreme cold to the selected site. Liquid nitrogen is forced through the cryoprobes under pressure. The cryoprobe, having been placed in the appropriate position through the used of utlrasound or other imaging device, then becomes cold and freezes the unwanted tissue. The procedure may be

monitored in real-time through the use of imaging modes such as ultrasound, Once the freezing is completed (approximately 20 minutes), the cryoprobe will be heated using warming gas in order to facilitate thawing and removal of the cryoprobe from the frozen tissue.

COMPARISON OF FEATURES BETWEEN THE AccuProbe® 600 Series [CLEARED 510(k) (K964336)] AND THE AccuProbe® 800 SERIES

FEATURES	AccuProbe® 600 Series	AccuProbe® 800 SERIES
Liquid Nitrogen Capacity (Dewar size)	Model 610 15 liters Model 620 25 liters Model 630 40 liters Model 640 55 liters Model 650 70 liters Model 660 85 liters Model 670 100 liters Model 680 115 liters	Model 810 25 liters Model 820 25 liters Model 830 25 liters Model 840 35 liters Model 850 35 liters Model 860 45 liters Model 870 45 liters Model 880 45 liters
Normal Operating Pressure	65psi	65psi
Regen/recirculating time	Two minutes	Less than 10 seconds
Regen mode	Depressurizes the supply dewar and pressurizes the return dewar (this allows capture of LN_2 to flow from the return dewar through the cryoprobe and back to the supply dewar)	The LN_2 return line from the cryoprobe feeds directly into the LN_2 supply
Dimensions	Model 610 45"x24"x29" Model 620 49"x24"x29" Model 630 52"x24"x29" Model 640 52"x24"x29" Model 650 54"x28"x32" Model 660 54"x30"x34" Model 670 54"x32"X34" Model 680 54"x32"x34"	Model 810 38"x24"x24" Model 820 38"24"x24' Model 830 38"24"x24" Model 840 38"x24"x24" Model 850 38"x26"x26" Model 860 38"x26"x26" Model 870 38"x26"x26" Model 880 38"26"x26"
Operation	Uses a three dewar system	Uses a one dewar system
Warming Gas	Nitrogen Gas	Nitrogen Gas

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Cryomedical Sciences, Inc.
c/o Mr. Richard J. Reinhart, Ph.D
President and CEO
1300 Piccard Drive, Suite L105
Rockville, MD 20850

Re: K982055
Trade Name: Accuprobe 800 Series Model Numbers: 810, 820, 830, 840, 850, 860, 870 and 880
Regulatory Class: II (two)
Product Code: OCL, GEH
Dated: June 11, 1998
Received: June 11, 1998

Dear Dr. Reinhart:

This letter corrects our substantially equivalent letter of September 8, 1998.

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 (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 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 continue 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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

The CMS AccuProbe® 800 Series (all models depicted as **A**) has the same indications for use as its predicate device, the AccuProbe® 600 Series [510(k) number K973190 cleared November 21, 1997].

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 K982055

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, 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.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982655

Prescription Use X
(Per 21 CFR 801.109)