JUL 17 1998

510(k) SUMMARY K980668

February 20, 1998

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 Blizzard 700 Series
Models 730, 740, 750, 760, 770, 780 & 790

Common name: Cryosurgical unit and accessories

Classification: A cryosurgical unit with liquid nitrogen nitrous oxide, or carbon dioxide cooled cryoprobe and accessories is classified in Class II under CFR § 878.4350. Under CFR § 882.4250, a cryogenic surgical device is also classified in Class II.

The CMS Blizzard 700 Series Models Models 730, 740, 750, 760, 770, 780 & 790 are made up of two components: 1) a console which holds up to two cryogen packets of varying sizes and 2) depending on the model, can employ from three to nine individually controlled cryoprobes. The consoles includes a power switch, individually controlled cryogen flow switches, thermocouple temperature displays and, depending on the model between three and nine cryoprobe ports.

The devices are used to destroy unwanted tissue by the application of cold to the selected site. The cryogen is forced through the cryoprobe under pressure. The cryoprobe, having been placed in the appropriate position, then becomes cold and freezes the tissue.

The CMS Blizzard 700 Series Models 730, 740, 750, 760, 770, 780 & 790 are similar in form and function to ENDOcare's CRYOcare System, as well as the CMS's own AccuProbe® Systems and its Cryo-lite™ System.

Comparison of Features Between the CMS Blizzard 700 Series Models730, 740, 750 , 760, 770, 780 and 790 AND ENDOcare's CRYOcare System

FEATURES	**ENDOcare's CRYOcare**	**CMS Blizzard Models 70, 740, 750, 760, 770, 780 & 790**
Cyrogens	Argon	Choice of liquid nitrogen, carbon dioxide, nitrous oxide, argon, and krypton, sequentially
Number of Cryoprobes	Up to eight Individually controlled cryoports	Depending on model, from three to nine individually controlled cryoports
Cryogen Containers	Commercial Cryogen Source	Cryogen packet and/or transfer line to larger cryogen source
Size	46"x19"x25" on Wheels	See specification sheet in Operation Manual
Cryoprobe Warming	Helium	Warming fluid such as circulated air
Cryoprobes Types	Two sizes, interchangeable	Various, interchangeable

Comparison of Features Between the CMS Blizzard 700 Series Models730, 740, 750 , 760, 770, 780 and 790 and the CMS AccuProbe® Systems

FEATURES	CMS AccuProbe® 450, 530/550 and 600 Series	CMS Blizzard Models 70, 740, 750, 760, 770, 780 & 790
Cyrogens	Liquid Nitrogen	Choice of liquid nitrogen, carbon dioxide, nitrous oxide, argon, and krypton
Number of Cryoprobes	Depending on Models, up to three, up to five or up to eight individually controlled cryoports	Depending on model, from three to nine individually controlled cryoports
Cryogen Containers	Commercial cryogen sources	Cryogen packet and/or transfer line to larger cryogen source
Size	See Operations Manuals for exact dimensions (Tab I, J , K) - on Wheels	See Specification Sheet in Operation Manual
Cryoprobe Warming	Nitrogen gas	Warming fluid , such as circulated air
Cryoprobes Types	Various, interchangeable	Various, interchangeable

Comparison of Features Between the CMS Blizzard 700 Series Models730, 740, 750 , 760, 770, 780 and 790 and CMS's Cryo-lite™ System

FEATURES	CMS Cryo-lite™	CMS Blizzard Models 70, 740, 750, 760, 770, 780 & 790
Cyrogens	Choice of nitrous oxide and carbon dioxide	Choice of liquid nitrogen, carbon dioxide, nitrous oxide, argon, and krypton
Number of Cryoprobes	One cryoprobe	Depending on model, from three to nine individually controlled cryoports
Cryogen Containers	Cryogen packets or commercial cryogen source through transfer line	Cryogen packets or commercial cryogen source through transfer line
Size	Portable - Hand-held	Portable - See Specification Sheet in Operation Manual
Cryoprobes Types	Various, interchangeable	Various, interchangeable

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: K980668
Trade Name: CMS Blizzard 700 Series
Models 730, 740, 750, 760, 770, 780 & 790
Regulatory Class: II (two)
Product Code: OCL, GEH
Dated: June 2, 1998
Received June 2, 1998

Dear Dr. Reinhart:

This letter corrects our substantially equivalent letter of July 17 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.

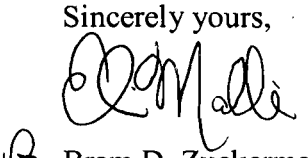
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Depending on the cryogen used, the following are indications for use:

Liquid Nitrogen:

For use as a cryosurgical tool for destruction of unwanted tissue in the fields of dermatology, general surgery, neurosurgery, thoracic surgery, urology, proctology, oncology, gynecology and ENT.

- May be used to ablate prostatic tissue.
- May be used for the ablation of prostatic tissue in cases of prostate cancer and benign prostatic hyperplasia.
- May be used for ablation of cancerous or malignant tissue.
- May be used for ablation of benign tumors.
- May be used for palliative intervention.
- May be used for ablation or freezing of skin cancers and other cutaneous disorders.
- May be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.
- May be used for ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid and canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, and fissures, peri-anal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions.
- May be used for the destruction of warts or lesions,
- May be used for the palliation of tumors of the oral cavity, rectum, and skin.
- May be used for ablation of arrhythmic cardiac tissue.
- May be used for the ablation of benign or malignant growths of the anus and rectum.
- 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 K980688

Indications for Use (continued)

Nitrous Oxide:

For use as a tool in the destruction of unwanted tissue in the fields of dermatology, gynecology, general surgery, urology, and veterinary medicine.

Carbon Dioxide:

For used as a tool in the destruction of unwanted tissue in the fields of dermatology, gynecology, and general surgery.

Argon and Krypton:

For use as a cryosurgical tool in general surgery, dermatology, neurology, thoracic surgery, ENT, gynecology, oncology, proctology, and urology for the ablation of tissue including liver metastases, skin lesions, warts and prostate tissue.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980668