

JUL 17 1998

K980670

510(k) SUMMARY

February 20, 1998

Submitted by:

Cryomedical Sciences, Inc.
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Contact:

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

Proprietary name: CMS Blizzard 700 Series
Models 710, 711, 712, 720, 721 and 722

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 Blizzard 700 Series Models 710, 711, 712, 720, 721 and 722 are simple, portable cryosurgical devices. All models feature physician-selected cryogen choices as well as a selection of cryoprobes of various sizes and shapes. Models 710, 711 and 712 are single cryoport devices while models 720, 721 and 722 have a two cryoport capacity. Although all models operate in the exact same way, their casings differ to allow desired positioning. The 710 and 720 are wheeled pole type configuration; the 711 and the 721 are tabletop configuration; while the 712 and the 722 are suitcase or attaché type configuration.

The CMS Blizzard 700 Series Models 710, 711, 712, 720, 721 and 722 are similar in form and function to CMS's own Cryo-lite™ System, and its AccuProbe® 600 Series, as well as Cabot Medical's Cryomedics MT700 and the Erbe Erbokryo CA. For comparisons, please see below.

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.

COMPARISON OF FEATURES BETWEEN THE CMS BLIZZARD 700 SERIES MODELS 710, 711, 712, 720, 721 AND 722 AND THE CMS CRYO-LITE™ SERIES .

FEATURES	Cryo-lite™ Series (Tab G)	Blizzard 700 Series Models 710, 711, 712, 720, 721 and 722
Cryogens	Choice of liquid nitrogen, carbon dioxide, nitrous oxide and argon which may be used sequentially	Choice of liquid nitrogen, carbon dioxide, nitrous oxide argon or krypton which may be used sequentially
Number of Cryoprobes	One cryoprobe	Models 710, 711 and 712 have a one cryoprobe capacity while models 720, 721 and 722 have a two cryoprobe capacity
Cryogen Containers	Cryogen packet and/or transfer line to larger cryogen source	Cryogen packet and/or transfer line to external cryogen source
Size	Portable and Hand-held	Portable,- Table-top or wheeled stand
Cryoprobes Types	Various, interchangeable	Various, interchangeable

COMPARISON OF FEATURES BETWEEN THE CMS BLIZZARD 700 SERIES
 MODELS 710, 711, 712, 720, 721 AND 722 AND THE CMS ACCUPROBE®
 600 SERIES

FEATURES	AccuProbe® Series (Tab H)	Blizzard 700 Series Models 710, 711, 712, 720, 721 and 722
Cryogens	Liquid nitrogen	Choice of liquid nitrogen, carbon dioxide, nitrous oxide argon or krypton which may be used sequentially
Number of Cryoprobes	Depending on the model, from one to eight cryoprobe ports	Models 710, 711 and 712 have a one cryoprobe capacity while models 720, 721 and 722 have a two cryoprobe capacity
Cryogen Containers	Internal cryogen container	Cryogen packet and/or transfer line to external cryogen source
Size	Portable	Portable,- Table-top or wheeled stand
Cryoprobes Types	Various, interchangeable	Various, interchangeable

COMPARISON OF FEATURES BETWEEN THE CMS BLIZZARD 700 SERIES
 MODELS 710, 711, 712, 720, 721 AND 722 AND THE CABOT MEDICAL
 CYROMEDICS MT700

FEATURES	Cryomedics MT700 (Tab I)	Blizzard 700 Series Models 710, 711, 712, 720, 721 and 722
Cryogens	Choice of nitrous oxide and carbon dioxide	Choice of liquid nitrogen, carbon dioxide, nitrous oxide, argon, or krypton
Number of Cryoprobes	One probe	Models 710, 711 and 712 have a one cryoprobe capacity while models 720, 721 and 722 have a two cryoprobe capacity
Cryogen Containers	Commercial Cryogen Container with Transfer Line to Probe	Cryogen packet and/or Transfer Line to external cryogen source
Size	Portable - Stand with wheels and hand-held probe	Portable, - Table-top or wheeled stand with hand-held cryoprobe
Cryoprobes Types	Various, interchangeable	Various, interchangeable

COMPARISON OF FEATURES BETWEEN THE CMS BLIZZARD 700 SERIES MODELS
710, 711, 712, 720, 721 AND 722 AND THE ERBE ERBOKRYO CA

FEATURES	Erbokryo CA (Tab J)	Blizzard 700 Series Models 710, 711, 712, 720, 721 and 722
Cryogen	Choice of nitrous oxide and carbon dioxide	Choice of liquid nitrogen, carbon dioxide, nitrous oxide, argon, or krypton
Number of Cryoprobes	One probe	Models 710, 711 and 712 have a one cryoprobe capacity while models 720, 721 and 722 have a two cryoprobe capacity
Cryogen Containers	Commercial cryogen container with transfer line to probe	Cryogen packet and/or transfer line to larger cryogen source
Size	Portable - Stand with wheels and hand-held Probe	Portable - Table-top or wheeled stand with and-held cryoprobe
Cryoprobes Types	Various, Interchangeable	Various, Interchangeable
Control	Foot switch	Console unit switch or foot pedal



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K980670
Trade Name: CMS Blizzard 700 Series
Models 710, 711, 712, 720, 721, 722
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.

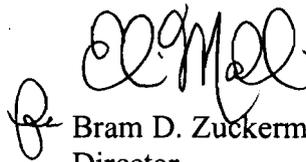
Page 2 - Mr. Richard J. Reinhart, Ph.D.

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" (21 CFR 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

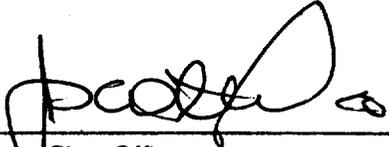
Indications for Use

The CMS Blizzard 700 Series Models 710, 711, 712, 720, 721 and 722, depending on the cryogen selected, are intended to be used:

Liquid Nitrogen:

- 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;
- to ablate prostatic tissue;
- for the ablation of prostatic tissue in cases of prostate cancer and benign prostatic hyperplasia;
- for ablation of cancerous or malignant tissue;
- for ablation of benign tumors;
- for palliative intervention;
- for ablation or freezing of skin cancers and other cutaneous disorders;
- for the ablation of malignant neoplasia or benign dysplasia of the female genitalia;
- 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;
- for the destruction of warts or lesions;
- for the palliation of tumors of the oral cavity, rectum, and skin;
- for ablation of arrhythmic cardiac tissue;
- for the ablation of benign or malignant growths of the anus and rectum;
- for the ablation of hemorrhoids;

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices

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Indications for Use (continued)

Nitrous Oxide:

- as a tool in the destruction of unwanted tissue in the fields of dermatology, gynecology, general surgery, and urology;

Carbon Dioxide:

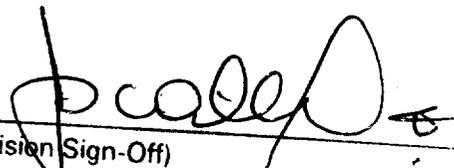
- as a tool in the destruction of unwanted tissue in the fields of dermatology, gynecology, and general surgery;

Argon and Krypton:

- 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 _____
(Per 21 CFR 801.109)

X



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____

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