K970995

# 510(k) SUMMARY

JUL - 7 1997

March 19, 1997

**Submitted by:**

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**Contact:**

Richard J. Reinhart, Ph.D.
President and CEO
or
Susan Hayes
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**Proprietary name:** CMS Cryolite

**Common name:** Cryosurgical Unit, Cryogenic Surgical Device or Cryoprobe

**Classification:** Cryosurgical unit with Liquid Nitrogen, Nitrous Oxide, Carbon Dioxide, Class II [21 CFR § 878.4350(a).

The CMS Cryo-lite® System is a completely disposable hand-held cryosurgical device. Both Cryo-lite® System Models 2001 and 2002 consist of hand-held body, a physician-selected cryogen packet and single cryoprobe of varying materials, sizes and shapes. Cryogens available with this system are liquid nitrogen, nitrous oxide, carbon dioxide and argon.

The Cryo-lite® System is used to destroy unwanted tissue by application of extreme cold to the selected site. The cryogen is forced through the cryoprobes under pressure. The cryoprobe, having been placed in the appropriate position through the use of ultrasound, another imaging device or visual observation then becomes cold 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.

The CMS Cryo-lite® System is similar in form and function to the Frigitronics' Cryocare I System and its Cryo Surg Model 5900 (K840536) and Cabot Medical's Cryomedics MT700. Intended use for the CMS Cryo-lite® System is the same as those listed for the CMS Cryolite® System predicate devices.

## COMPARISON OF FEATURES BETWEEN THE FRIGITRONICS MODEL 5900 SYSTEM AND THE CMS CRYO-LITE SYSTEM

| FEATURES | Frigitronics 5900 | Cryolite System |
|---|---|---|
| Cryoprobes | Spray and closed-tip | Spray and closed-tip |
| Cryoprobes | Various, interchangeable | Various, interchangeable |
| Power source | Non-electric | Non-electric |
| Cryogen | Liquid nitrogen | Choice of liquid nitrogen, carbon dioxide, nitrous oxide and argon |
| Flow control | Adjustable flow rates, trigger type | Dial with flow rate markings |
| Size | Portable, hand-held | Portable, hand-held |
| Capacity | 500 ml cryogen container | 9 oz. cryogen packet and different capacities depending on commercial cryogen containers used with transfer line |

## COMPARISON OF FEATURES BETWEEN THE CRYOMEDICS MT700 SYSTEM AND THE CMS CRYO-LITE SYSTEM

| FEATURES | Cryomedics MT700 | Cryolite System |
|---|---|---|
| Cryogen | Choice of nitrous oxide and carbon dioxide | Choice of liquid nitrogen, carbon dioxide, nitrous oxide and argon |
| Flow control | Dial with flow rate control | Dial with flow rate markings |
| Size | Portable, hand-held | Portable, hand-held |

## COMPARISON OF FEATURES BETWEEN THE FRIGITRONICS MODEL CS-76/CRYOCARE I SYSTEM AND THE CMS CRYO-LITE SYSTEM

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| FEATURES | Frigitronics CS-76/Cryocare I | Cryolite System |
|---|---|---|
| Cryoprobes | Spray and closed-tip | Spray and closed-tip |
| Cryoprobes | Various sizes and materials , interchangeable | Various sizes and materials, interchangeable |
| Power source | Non-electric | Non-electric |
| Cryogen | Liquid nitrogen | Liquid nitrogen, carbon dioxide, nitrous oxide and argon |
| Flow control | Adjustable flow rates, trigger type | Dial with control markings |
| Size | Portable, hand-held trigger with $LN_2$ transfer line attached to $LN_2$ vacuum insulated containers | Portable, hand-held, with cryogen packet or cryogen transfer line to an external cryogen source |
| Capacity | 1 liter | 9 oz. cryogen packet and different sizes of commercial cryogen containers used with transfer line |

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
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1300 Piccard Drive
Rockville, Maryland 20850-4303

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Re: K970995
Trade Name: CMS Cryolite
Regulatory Class: II
Product Code: GEH
Dated: June 19, 1997
Received: June 20, 1997

Dear Dr. Reinhart:

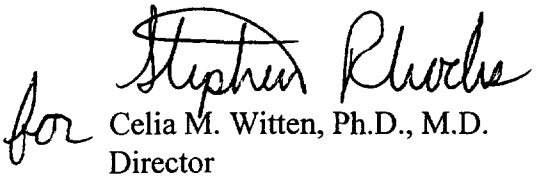
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 (Premarket Approval), 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 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. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission 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 device as described in your 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 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 device, 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,



for 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

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# Indications For Use

The CMS Cryo-lite® System has the same indications for use as its predicate devices, the Frigitronics Model 5900, Frigitronics Cryocare I and the Cryomedics Model MT700 . The Cryo-lite® System is intended to be used as a cryosurgical tool for destruction of unwanted tissue in the fields of dermatology, gynecology general surgery, etc. and veterinary medicine.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970995

Prescription Use Y
(Per 21 CFR 801.109)

Over-the-Counter Use _____