OCT - 1 1997

CryoGen, Inc.
San Diego, CA
Premarket Notification
July 2, 1997

K972662

X. 510(k) Summary

Name of Device

Trade name:	CryoGen Cryosurgery System
Common name:	Cryosurgical Unit and Accessories
Classification name:	Cryosurgical Unit and Accessories (21 CFR 878.4350)

Predicate devices

Device	Premarket Notification
Frigitronics CE-4 & CE-4G	Pre-Amendment
Frigitronics CCS 100	K811390
CMS AccuProbe	K904421
CMS AccuProbe 550/530	K953637
CryoGen Cryosurgical System 1	K964971

Device description & Principle of Operation

The CryoGen Cryosurgery System consists of three components: the disposable Control Unit, the Cryoprobe and the Console, which contains the compressor system, microprocessor and user interface. The CryoGen Cryosurgery System is a cryosurgical device incorporating a gas cooled cryoprobe. Operation of the System is based on the Joule-Thomson principle in which pressurized coolants are expanded through a small orifice to produce cooling. The device is intended to destroy tissue by the application of extreme cold. Temperatures of -100 to -120 °C are developed at the tip of the cryoprobe. These temperatures are within the range of the predicate devices and is sufficient to achieve the desired tissue effect. None of the coolant comes into contact with the patient or physician. In addition, none of the coolant gases are exhausted into the atmosphere, the system is closed. There is no cooling along the shaft of the probe nor at the handle that is held by the user during treatment.

Intended use

The CryoGen Cryosurgical System is intended for use in the surgical ablation of tissue by the application of extreme cold in the fields of dermatology, general surgery, neurosurgery, thoracic surgery, E.N.T., gynecology, oncology, proctology and urology. This intended use is identical to the intended use for the predicate cryosurgical devices.

Technological characteristics

The technological characteristics of the CryoGen Cryosurgical System 2 are the same as those of the CryoGen Cryosurgical System 1, and the other predicates listed elsewhere in this premarket notification. These devices are substantially equivalent in terms of design, materials, principle of operation, product specifications and sterilization.

Summary

By virtue of design, materials, function and intended use, the CryoGen Cryosurgical System 2 is substantially equivalent to the CryoGen Cryosurgical System 1 which is cleared under K964971. It is also equivalent to the predicate devices, both pre-amendment and cleared via the Premarket Notification process, which have been included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Cheryl L. Shea,
Vice President Regulatory Affairs/Quality Assurance
CryoGen, Inc.
6199 Cornerstone Court East
Suite 106
San Diego, California 92121

OCT - 1 1997

Re: K972662
Trade Name: CryoGen Cryosurgery System
Regulatory Class: II
Product Code: GEH
Dated: July 2, 1997
Received: July 3, 1997

Dear Ms. Shea:

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.

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 approval of a premarket approval application (PMA) 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 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) 594-4639. 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, M.D., Ph.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: CryoGen Cryosurgical System
510(k) Number:

Indications for use:

The CryoGen Cryosurgical System is indicated for the ablation of tissue by the application of extreme cold in the areas of dermatology, general surgery, neurosurgery, thoracic surgery, E.N.T., gynecology, oncology, proctology and urology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971662

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)