DEC 22 1997

Section II - SMDA 1990 Requirements

K973686

Safety and Effectiveness Summary

Device Description

The ENDOcare CRYOcare™ Cryosurgical System consists of a console which can control one to eight single-use, disposable CRYOprobes™ and one to eight independent inputs to monitor temperatures from standard T-type needle thermocouples. The system is compact and operates off of standard 110 VAC wall power.

Several models will be provided depending on the needs of the customer. Currently, the system is available in a 1, 4 and 8-CRYOprobe™ configuration. The performance characteristics and internal design of each model are equivalent. The only differences are the number of valves to control the CRYOprobes™ (e.g., 1-8), number of thermocouple inputs (e.g., 1-8) and the size of the outer case.

Indications for Use

The ENDOcare CRYOcare™ Cryosurgical System is intended for use in general surgery, urology, gynecology, oncology, neurology, thoracic surgery, dermatology, ENT, and proctology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate, kidney, and breast tissue, liver metastases, tumors, skin lesions, and warts.

Substantial Equivalence

The ENDOcare CRYOcare™ CRYOsurgical System is substantially equivalent to the ENDOcare 8-probe system which was cleared on January 19, 1995 (reference K942299) and the 2 and 5-probe system which was cleared on December 18, 1996 (reference K963826). The ENDOcare system is also substantially equivalent to the Urosprobe System Model 1000 which was cleared on April 1, 1996 (reference K960387).

Sterilization Methodology

The following sterilization information is applicable to the CRYOprobes™ only. Sterilization validation was based on the recommendations in the current AAMI (American Association for the Advancement of Medical Instrumentation) Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices. A minimum Sterility Assurance Level (SAL) of 10^{-6} was achieved. Sterile barrier packaging consists of standard disposable medical device packaging containing a plastic film and a coated paper side. Maximum levels of EtO residuals did not exceed:

25 ppm for ethylene oxide
25 ppm for ethylene chlorohydrin
250 ppm for ethylene glycol

Shelf Life Determination

Ten (10) simulated products and one (1) control were packaged, sealed and processed through a full sterilization cycle to replicate sterilization parameter effects on package seal integrity. Following sterilization, the packaged CRYOprobes™ were submitted to an outside testing laboratory for accelerated aging equivalent to one year using the following parameters:

2.5 weeks at 55°C and 75 ± 5% relative humidity
24 hours at -15°C + 5°C
2.5 weeks at 55°C and <20% relative humidity

Following accelerated aging, the CRYOprobes™ were shipped to another facility via UPS ground service. The packages were then returned via UPS Second Day Air Service. The purpose of this test was to simulate conditions that the product might experience in shipping and handling.

Following the environmental challenge, the samples were subjected to a microbial challenge and tested to determine if microbial penetration has occurred. Functional testing was conducted pre- and post-accelerated aging. All test results met the acceptance criteria equivalent to a one year shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

Mr. Vin Cutarelli
Vice President, Regulatory Affairs and Quality Assurance
Endocare, Incorporated
7 Studebaker
Irvine, California 92618

Re: K973686
Trade Name: ENDOcare CRYOcare™ Cryosurgical System
Regulatory Class: II
Product Code: GEH
Dated: September 25, 1997
Received: September 26, 1997

Dear Mr. Cutarelli:

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.

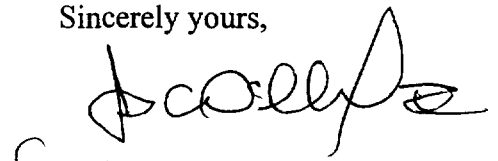
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

Indication For Use Statement

510(k) Number: K973686

Device Name: ENDOcare CRYOcare™ Cryosurgical System

The ENDOcare CRYOcare™ Cryosurgical System is intended for use in general surgery, urology, gynecology, oncology, neurology, thoracic surgery, dermatology, ENT, and proctology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate, kidney, and breast tissue, liver metastases, tumors, skin lesions, and warts.

Concurrence of CDRH, Office of Device Evaluation (ODE):

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973686

Prescription Use: X
(Per 21 CFR 801.109)