

K 980118
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APR 10 1998

Section II - SMDA 1990 Requirements

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.

The system is available in 1, 4 and 8-CRYOprobe™ configurations. 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, and kidney tissue, liver metastases, tumors, skin lesions, and warts. In addition, the system is intended for use in the following indications:

Urology

- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

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General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions

Thoracic Surgery

- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

Proctology

- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

Substantial Equivalence

The ENDOCare CRYOcare™ CRYOsurgical System is substantially equivalent to the Cryomedical Sciences, Inc. AccuProbe® models which were found to be substantially equivalent on November 21, 1997 (reference K973190) and the ENDOCare cryosurgical system which was determined to be substantially equivalent on December 22, 1997 (K973686).

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. The packaging consists of a 16" x 28", straight seal, 10-59B Tyvek/Polyester (48 ga.)/Polyethylene pouch. Maximum levels of EtO residuals did not exceed:

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



FEB 21 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Endocare, Incorporated
c/o Mr. Vin Cutarelli
Vice President
Regulatory Affairs & Quality Assurance
7 Studebaker
Irvine, CA 92618

Re: K980110
Trade Name: ENDOcare CRYOcare™ Cryosurgical System
Regulatory Class: II (two)
Product Code: OCL, GEH
Dated: January 9, 1998
Received: January 12, 1998

Dear Mr. Cutarelli:

This letter corrects our substantially equivalent letter of November 29, 2004.

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.

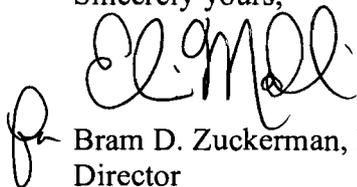
Page 2 - Mr. Vin Cutarelli

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,

A handwritten signature in black ink, appearing to read "B. Zuckerman". The signature is written in a cursive style with a large initial "B" and "Z".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use Statement510(k) Number: K980110

Device Name: ENDOCare CRYOcare™ Cryosurgical System

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Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

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

for cmw


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980110
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Prescription Use: X
(Per 21 CFR 801.109)

Indications for Use (continued):

General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
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for cmw

 (Division Sign-Off)
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