FEB 2 5 2005



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# 510(K) SUMMARY

K050347

**Prepared – December 12, 2004**

| | | | |
|---|---|---|---|
| TRADE NAME | Cryocare CS Surgical System | | |
| COMMON NAME | Cryosurgical unit and accessories | | |
| CLASSIFICATION | Class II (21 CFR 878.4350) | | |
| SUBMITTED BY | Endocare, Inc.<br>201 Technology<br>Irvine, CA 92618 | **CONTACT** | Eben Gordon<br>Regulatory Affairs<br>949.450.5424<br>949.450.5300 |
| PREDICATE DEVICE | **K032333** - Endocare Cryocare CS Surgical System<br>Decision date: 8/18/2003<br>**K043278** – Teratech Model 8IOC4, 8IOL4, 10LAP4 Probe<br>Decision date: 12/13/2004 | | |
| DEVICE DESCRIPTION | The Cryocare CS Surgical System consists of a compact, easy-to-operate console that delivers cold temperatures to targeted tissue (via connected CryoProbes) and monitors temperatures in the surrounding tissue (via connected TempProbes).<br><br>The Cryocare CS Surgical System has a fold-down 19" LCD high-resolution display screen, a video printer for hard copy prints of the captured images and patient information, a CD-R/W drive for data storage and retrieval, an alphanumeric keypad and a remote keypad.<br><br>The Cryocare CS Surgical system unit integrates the functions of the existing Cryocare surgical system and the CryoGuide system into one console. The CryoGuide software is an optional brachy-like intraoperative real-time guidance and planning system, which identifies and guides CryoProbe placement for prostate procedures.<br><br>The Cryocare CS Surgical System has an ultrasound system with available a trans-rectal transducer for prostate imaging or a laparoscopic transducer. The transducers operate in B, Power Doppler, Color Doppler (including directional and non-directional Power Doppler), and Harmonic Imaging. The Trans-rectal transducer is capable of transverse and sagittal views.<br><br>Ultrasound images may be obtained either from an external ultrasound (via video connection) or the integrated ultrasound module. The user screen simultaneously displays the real-time ultrasound image along with the treatment screen. For prostate procedures, the treatment screen displays the prostagraph showing the anatomical CryoProbe and TempProbe placements and associated temperature readings.<br><br>The 10LAP4 Probe is intended for use with Cryocare CS Surgical System's ultrasound imaging system. Technical specifications for the probes is as follows: | | |

| | |
|---|---|
| Frequency | 7.0 MHz |
| # Elements | 128 |
| Array type | Linear |
| Pitch (mm) | 0.30 |
| Elevation width (mm | 5.0 |
| Geometric focus (mm) | 25 |
| Azimuth radius (mm | N/A |
| Azimuth length (mm | 38.4 |

The Cryocare CS Surgical System can control up to eight, single-use, disposable CryoProbes and monitor up to eight independent TempProbes. The console operates off standard 120/230 VAC (60/50 Hz) wall power and utilizes inert argon and helium gas. An IBM compatible microprocessor serves as the host computer operating in a Windows environment. CryoProbe control can also be achieved via the remote control keypad. The CryoProbes can be operated manually or using the AutoFreeze mode, which allows users to pre-program specific prostate treatment parameters.

**INDICATIONS FOR USE**

The Cryocare CS Surgical System has the **same intended use** as previously cleared for the Cryocare CS Surgical System - K032333.

The Cryocare CS Surgical System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The intended use of the 10LAP4 probe, when used as a part of the Cryocare CS Surgical System, is for diagnostic ultrasound imaging or fluid flow analysis of the human body and is a subset of the uses cleared under K043278, and is documented in Section 4.3 of this submission.

**SUMMARY OF SUBSTANTIAL EQUIVALENCE**

The Cryocare CS Surgical System has the following similarities to that of the previously cleared predicate devices:

- Has the same intended use;
- The 10LAP4 ultrasound probe is the same as Teratech's cleared under K043278 and is intended for the same clinical application;
- Use the same operating principle and has not altered the fundamental technology;
- Incorporate the same CryoProbe;
- Incorporate the same system design;
- Incorporate the same patient contacting materials;
- Same manufacturing materials; and
- Packaged and sterilized using the same materials and processes.

In summary, the modified Cryocare CS Surgical System described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Endocare, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K050347
Trade/Device Name: Cryocare CS Surgical System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II (two)
Product Code: OCL, GEH, IYN, ITX
Dated: February 7, 2005
Received: February 11, 2005

Dear Mr. Job:

This letter corrects our substantially equivalent letter of February 25, 2005.

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.

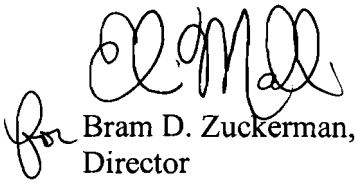
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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,



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

Enclosure

# Indications for Use Statement

510(k) Number: K050347

Device Name: **Cryocare CS Surgical System**

**Indications for Use:**
The Cryocare CS Surgical System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate 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:

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

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

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

**Prescription Use __X__ (Per 21 CFR 801.109)**

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K050347

## Indications for Use Statement (Continued)

Urology

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

Gynecology

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

Oncology

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

Neurology

- Freezing of nerve tissue in pain management/cryoanalgesia

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Proctology

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

Thoracic Surgery

- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

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

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

PRESCRIPTION USE __X__ (PER 21 CFR 801.109)