



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 5, 2016

Health Tronics, Inc.  
Maritza Ward  
Manager, Regulatory Affairs  
9825 Spectrum Dr., Bldg. 2  
Austin, Texas 78717

Re: K153489

Trade/Device Name: Cryocare CS Surgical System  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical Unit and Accessories  
Regulatory Class: Class II  
Product Code: GEH  
Dated: December 2, 2015  
Received: December 4, 2015

Dear Ms. Ward:

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 application (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Jennifer R. Stevenson -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K153489

Device Name  
Cryocare CS Surgical System

### Indications for Use (Describe)

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 breast fibroadenomas
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions

#### 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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

---

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
*PRASStaff@fda.hhs.gov*

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*



**Cryocare CS® Surgical System  
510(k) Summary-K153489**

**COMPANY:** Endocare, a wholly owned subsidiary of HealthTronics, Inc.  
9825 Spectrum Drive, Building 2  
Austin, TX 78717

**CONTACT:** Maritza Ward, B.S.  
Manager, Regulatory Affairs  
Email: maritza.ward@healthtronics.com  
Telephone: (512) 439-8361  
Fax: (512) 439-8311

**PROPRIETARY TRADE NAME** Cryocare CS® Surgical System

**CLASSIFICATION NAME:** Cryosurgical Unit and Accessories

**CLASS:** II

**PRODUCT CODE:** GEH

**REGULATION NUMBER:** 21 CFR 878.4350

**PREDICATE DEVICE:**

Cryocare Surgical System	K003811	Cleared 10/11/2001
Cryocare CS Surgical System	K141110	Cleared 06/25/2015
Cryocare CS Surgical System	K151968	Cleared 09/09/2015
Galil Medical Visual ICE	K143564	Cleared 03/05/2015
Galil Medical IceEDGE	K111859	Cleared 10/07/2011
Galil Medical IceRod	K140584	Cleared 03/31/2014

**PRODUCT DESCRIPTION:**

The Endocare™ Cryocare CS® Surgical System is a mobile console system intended for cryoablative tissue destruction. The system consists of a compact, easy to operate console and associated accessories that include cryoprobes to deliver cold temperatures to the targeted tissue, and TempProbe® devices to monitor temperatures in the surrounding tissue.

**Cryocare CS® Surgical System  
510(k) Summary-K153489**

**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 breast fibroadenomas
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions

**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

**Cryocare CS® Surgical System  
510(k) Summary-K153489**

**TECHNOLOGICAL CHARACTERISTICS:**

The proposed Cryocare CS Surgical System console and cryoprobe designs are identical to their predicates with the exception of

- Addition of previously cleared indication for use: “Ablation of breast fibroadenoma”
- Addition of the Cryocare CS Basic Console (CRYO-CS Basic)
- Addition of the 2.4 mm Right-Angle Variable Probe (CVA2400RA)
- Addition of new part numbers associated with packaging configuration changes

The subject designs have the same fundamental technological features and intended use and are compatible with the same Cryocare CS Surgical System consoles and accessories as their predicate designs.

**NON-CLINICAL TESTING**

Appropriate product testing was performed on all subject devices to evaluate conformance to product specifications and equivalence to the predicate designs. Verification and validation for the proposed modifications were conducted in accordance with internal protocols conforming to international standards and FDA guidance documents.

Verification /Validation Activities

- Performance Testing
  - Isotherm Testing
- Packaging Integrity Testing
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Software Verification and Validation

**CONCLUSION:**

Based on a comparison of indications for use, technological characteristics and isotherm data, the proposed devices have demonstrated substantial equivalence to their predicates and are shown to be safe and effective for their intended use.