K110754

SEP - 9 2011

510(k) Summary of Safety and Effectiveness

CryoPen, Inc.
CryoPen Cryosurgical System
Traditional 510(k)

A. General Information

Applicant:	CryoPen, Inc.
Address:	2010 E. Continental Blvd. Suite D Southlake, TX 76092
Contact Person:	Dr. Michael Haas
Telephone:	888-246-3928
Facsimile:	817-549-0012
Date Prepared:	April 25, 2011
Device Trade Name:	CryoPen Cryosurgical System
Common Name:	Cryosurgical Unit and Accessories
Classification Name:	Unit, Cryosurgical, Accessories

B. Description of the Device

The CryoPen system provides a safe means of freezing tissue without the use of cryogenic liquids or greenhouse gases. The system consists of multiple pen cores, a Stirling cooler which rejects heat, and a variety of reusable tips for dermatologic and gynecology applications. When used properly, the system will deliver effective temperature for tissue ablation. The model number of this Cryosurgical system is CT-2000.

The Stirling cooler is used to lower the temperature of the CryoPen units to temperatures of -105 degrees Celsius. It operates on a 24 V DC external power supply powered by 115 (or 220) V AC obtained from conventional convenience outlets. The housing of the cooler provides necessary electrical safety features and electromagnetic compatibility. A temperature indicator indicates the readiness of the CryoPen units during cool down.

There are currently four different size tips for use in general surgery and dermatological applications as well as four different size tips for use in gynecology applications. They are:

Application	**Tip Sizes**
General/Dermatology	3mm, 5mm, 7mm, 10mm
Gynecology	3mm, 10mm, 19mm, 25mm

C. Intended Use Statement

Cryosurgical unit used for ablative type surgical technique on multiple organ systems, wide range of disease, viral, premalignant and malignant tissue.

Cryosurgical instrument used to necrose unwanted tissue, generally in the gynecological and dermatological practice

D. Components

CONTENTS:	**ITEM NUMBER:**
Base Unit	
CryoPen® Cooling System Assembly (1ea.)	CT-2000
Reservoir Solution 500ml (1ea.)	CT2-RS-1001
Reservoir Tube- Plastic (23ml)	CT2-RS-1002
Reservoir Tube Cap (1ea.)	CT2-RS-1003
Cleaning Swabs –Single end 14"(6)	CT2-SW-1000
Transfer Pipette- ½ dozen	CT2-PP-1000
CryoPen® Operators Packet	CT2-OP1000
General/Dermatological Configuration	
Non-Sterile re-usable CryoPen® tip (1ea.) 3mm	CT2-T-5003
Non-Sterile re-usable CryoPen® tip (1ea.) 5mm	CT2-T-5005
Non-Sterile re-usable CryoPen® tip (1ea.) 7mm	CT2-T-5007
Non-Sterile re-usable CryoPen® tip (1ea.) 10mm	CT2-T-5010
Pen Core – Blue (4)	CT2-C-1000
Temperature Indicator (Grey) (1ea.)	CT2-T1-1000
Gynecological Configuration	
Non-Sterile GYN Handle (1 ea.)	GY2-1100
GYN Pen Cores - Green (2 ea.)	GY2-2201
Non-Sterile Re-usable CryoPen® tip (1ea.) 3mm	GY2-2303
Non-Sterile re-usable CryoPen® tip (1ea.) 10mm	GY2-2310
Non-Sterile re-usable CryoPen® tip (1ea.) 19mm	GY2-2319
Non-Sterile re-usable CryoPen® tip (1ea.) 25mm	GY2-2324
Blank Core (1ea.)	GY2-3001
Temperature Indicator (Green) (1ea.)	GY2-4100

E. Substantial Equivalence

The CryoPen cryosurgical system is substantially equivalent to the Wallach LL100 Predicate Device, approved on February 4, 1981, (reference K803311) based on the nonclinical bench testing performed on ballistic gelatin. Data generated from bench testing shows the CryoPen is able to freeze the same volume and mass as the Wallach LL100.

The CryoPen and the Wallach LL100 destroy tissue using cryogenic temperatures. However, the CryoPen does not rely on a cryogenic gas such as nitrous oxide or carbon dioxide for cryoablation. Instead, the CryoPen uses a chilled copper mass fashioned into a treatment medium. The contacting metal incorporated in the cryotips used with the CryoPen are made of aluminum, which differs from the predicate contact material of stainless steel. Appropriate biocompatibility and sterility testing was performed on the aluminum cryotips used in the CryoPen and accessories.

The modified CryoPen and accessories have the following similarities to those which previously received 510(k) concurrence:

- have the same indicated use,
- destroy unwanted tissue by cryoablation, and
- method of sterilization

The Wallach LL100 510(k) K803311 has indications of "a cryosurgical instrument used to necrose unwanted tissue, generally in the gynecological and dermatological practice". The CryoPen and Accessories has clearance as a Cryosurgical unit used "for ablative type surgical technique" with use on "multiple organ systems, wide range of disease, viral, premalignant and malignant tissue." Additionally, the CryoPen system is adding the same intended use as the LL100 for use in the gynecological and dermatological practices.

Additionally, the CryoPen and Accessories uses the same sterilization methods as the Wallach LL100, cold soak and autoclave.

In summary, the CryoPen and Accessories described in this submission are substantially equivalent to the predicate device as the safety, efficacy, and intended use are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CyroPen, Inc.
% Michael Haas, M.D.
2010 East Continental Boulevard
Suite D
Southlake, Texas 76092

SEP - 9 2011

Re: K110754
Trade/Device Name: CyroPen and Accessories (Model: CT-2000)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cyrosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: August 31, 2011
Received: September 01, 2011

Dear Dr. Haas:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

For Mark N. Melkerson mp 1/6 DEP CLR DIR

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number **K110754**

Device Name **CryoPen and Accessories (Model: CT-2000)**

Indications for Use

Cryosurgical unit used for ablative type surgical technique on multiple organ systems, wide range of disease, viral, premalignant and malignant tissue.

Cryosurgical instrument used to necrose unwanted tissue in the gynecological and dermatological practice

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110754