FEB - 9 2011

PREMARKET NOTIFICATION
Traditional 510(K) SUMMARY

K103310

Submitter's Name:	3JT Enterprises, LLC., dba CryoNize
Address:	2000 N. Racine Ave., Suite 3100, Chicago, IL 60614
Telephone Number:	(312)-952-5462
Fax Number:	866-379-5579
Contact Person:	Anthony K. Goldboss, M.D.
Date Prepared:	November 7th, 2010

Device Name:

Proprietary Name:	CryoNize™
Usual Name:	CryoNize™

Devices to Which Substantial Equivalence is Claimed:

Histofreezer® Device, by OraSure Technologies, Inc. **(Primary Predicate including general labeling and flammability label)** – K023487, K990877, K971392, K933327, K931299, K924114, K911420, K982358.

Verruca-Freeze Cryosurgery Delivery System™, by CryoSurgery, Inc. **(Secondary Predicate including labeling)** – K982506, K955083, K944221, K881349.

Device Classification:

CryoNize™ is a cryogenic device classified under 21 CFR 878.4350 as a Class II medical device. The general and plastic surgery panel cryogenic classification name for a cryosurgical unit and accessories is product code GEH.

Description of Device:

CryoNize™ is a cryosurgical system used for the treatment of Verruca Vulgaris, Verruca Plantaris, Condyloma Acuminata, Verruca Plana, Molluscum Contagiosum, Skin Tags, Seborrhoeic Keratosis, Actinic Keratosis, and Lentigo.

It consists of:

- An aerosol canister filled with a liquid mixture of compressed gases. This mixture, or cryogen, is composed of 95% dimethyl ether, 2% propane, and 3% isobutane (118 ml).
- Customized applicators
  - CryoNize™ Foam Tip Applicators–two different shapes/sizes
  - CryoNize™ Zone Applicators–six different sizes (3mm, 5mm, 7mm, 9mm, 12mm, 15mm)
- Instructions for Use Booklet
- Quick Guide for Use
- Carrying Case
- Practice Mouse Pad

Performance Standards:

To date, no performance standards have been finalized which affect this device.

Intended Use Statement:

CryoNize™ is indicated, for medical professional use only, in the treatment of Verruca Vulgaris, Verruca Plantaris, Condyloma Acuminata, Verruca Plana, Molluscum Contagiosum, Skin Tags, Seborrhoeic Keratosis, Actinic Keratosis, and Lentigo.

Comparision of Technological Characteristics:

CryoNize™ is for the treatment of Verruca Vulgaris, Verruca Plantaris, Condyloma Acuminata, Verruca Plana, Molluscum Contagiosum, Skin Tags, Seborrhoeic Keratosis, Actinic Keratosis, and Lentigo. It is substantially equivalent to the Histofreezer® Device (K023487) and the Verruca-Freeze™ Cryosurgery Delivery System (K982506).

All three devices are portable aerosol cryosurgical systems that contain a canister filled with cryogen and foam tip applicators. When the cryogen is dispensed, it saturates the foam tip. The foam tip is then applied directly to the desired area of treatment. Subsequently, this freezes the skin lesion. These devices are substantially equivalent.

CryoNize™ has a second type of applicator which can be used, like Verruca-Freeze™ Cryosurgery Delivery System. CryoNize™ Zone Applicators are substantially equivalent to Verruca-Freeze™ Cryosurgery Delivery System Limiting Cones.

Labeling:

The labeling of CryoNize™ has been prepared to ensure the medical professional has adequate and clear instructions for safety and usage. It includes carrying case and canister labeling, Instructions for Use Booklet, and a Quick Guide for Use. The labeling, safety and warning statements are substantially equivalent to the predicate devices.

Conclusion:

Based on the information presented above, it is concluded that the proposed CryoNize™ is safe and effective for its intended use and is substantially equivalent to the primary and secondary predicate devices. Also, the labeling is substantially equivalent to the predicate devices.

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

3JT Enterprises, LLC
% Anthony K. Goldboss, M.D.
2000 North Racine Avenue, Suite 3100
Chicago, Illinois 60614

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Re: K103310
Trade/Device Name: CyroNize™
Regulation Number: 21 CFR 878.4350
Regulation Name: Cyrosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: January 11, 2011
Received: January 18, 2011

Dear Dr. Goldboss:

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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K103310

Device Name: CryoNize™

Indication for Use: CryoNize™ is indicated for use in the treatment of the following:

Verruca Vulgaris, Verruca Plantaris, Condyloma Acuminata, Verruca Plana, Molluscum Contagiosum, Skin Tags, Seborrhoeic Keratosis, Actinic Keratosis, and Lentigo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) Number K103310

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____