K102006

CryOmega

PREMARKET NOTIFICATION SUMMARY

I. Device Name:

Proprietary Name – CryOmega
Usual Name – Cryosurgical unit and accessories
Classification Name – Class II, GEH

OCT 6 2010

II. Establishment Registration Number:

This 510(k) is submitted by STC Consulting LLC. The product will be manufactured by CryoConcepts LLP, a company owned by STC Consulting LLC.

III. Device Classification:

The CryOmega is a Class II device according to Cryosurgical unit and accessories (21 CFR 878.4350) and has been assigned a product code of GEH.

IV. Performance Standards:

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

V. Proposed Labels, Labeling, Advertisements and Engineering Drawings:

This document contains the proposed Instruction Manual for the CryOmega device

VI. Statement of Similarities and Differences to Legally Marketed Devices:

A summary of the substantial equivalence ("SE") analysis for the CryOmega versus the Cryoprobe-C is provided in the following table.

510k Predicate Characteristic	Cryoprobe-C Predicate K024009	CryOmega-Substantial Equivalence
Cryoprobe-C K024009 -Intended Use Statement	Intended Use: To destroy tissue during surgical procedures by applying extreme cold	The CryOmega is a disposable device intended for the surgical destruction of target tissue by applying cryogenic gases at extreme

		low temperatures. The list below shows examples of the type of lesions that can be treated. -Genital Lesions -Molluscum Contagiosum -Seborrheic Keratoses -Skin Tags -Verruca Plantaris -Verruca Vulgaris -Verruca Plana -Actinic Keratosis -Lentigo
Cryoprobe-C K024009 **-Cryogen Characteristics**	Nitrous Oxide, N2O at 50 bar pressure. 8g or 16g cartridges	Nitrous Oxide, N2O at 50 bar pressure. 16g cartridge
Cryoprobe-C K024009 **-Materials**	Housing: Aluminum Micro-Applicator: unknown Lock Cap: Plastic Filter: Unknown O-rings: Unknown Cartridge: Metal	Housing: Plastic Filter: Plastic O-rings: Butadiene-rubber Cartridge: Metal
Cryoprobe-C K024009 **-Mode of Use**	Apply Spray Topically	Apply Spray Topically
Cryoprobe-C K024009 **-Mechanism of action**	N20 gas is delivered to the treatment site at -89C to effect cellular destruction	N20 gas is delivered to the treatment site at -89C to effect cellular destruction
Cryoprobe-C K024009 **-Storage Conditions**	<50°C	<50°C
Cryoprobe-C K024009	Complies with ASTM: F882-84 (96) for	Complies with ASTM: F882-84 (96)

-Safety	Cryosurgical Medical Instruments	for Cryosurgical Medical Instruments
Cryoprobe-C K024009 **-Gas Cartridge Safety**	Cartridge can expel unused gas under pressure during cartridge replacement	Unit is discarded after liquefied gas is emptied.
Cryoprobe-C K024009 **-Treatment Procedure**	Suggests Freezing of target tissue by spray	Same
Cryoprobe-C K024009 **-Operation**	Spray begins when gas cartridge is engaged. Continuous spray unless capped	Gas dispensed using actuator lever. Spray controlled by on/off actuator
Cryoprobe-C K024009 **-Disposal**	Main Unit is reusable with replaceable gas cartridges	Whole Unit is disposable after liquefied gas is emptied from the cartridge.
Cryoprobe-C K024009 **-Defined Operators**	Physician or Licensed Practitioner	Same
Cryoprobe-C K024009 **-Service/Repair**	Return to Manufacturer	Disposable once liquefied gas is emptied. No Servicing

It is believed that the data presented in the Testing Section of this submission is sufficient to demonstrate substantial equivalence between the predicate and CryOmega Device.

Intended Use

The CryOmega is a disposable device intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures. The list below shows examples of the type of lesions that can be treated.

-Genital Lesions
-Molluscum Contagiosum
-Seborrheic Keratoses
-Skin Tags
-Verruca Plantaris
-Verruca Vulgaris
-Verruca Plana

-Actinic Keratosis
-Lentigo

Technological Characteristics

The CryOmega device is designed to dispense a continuous stream of liquid nitrous oxide when actuated. The device contains a 16g cartridge of nitrous oxide that is dispensed once the device is activated. Physicians or medical professionals can then dispense the gas for use in procedures requiring the destruction of tissue using the extreme cold of nitrous oxide (-89°C). Unlike the predicate device, the CryOmega is designed to be self contained and disposable after all of the liquefied gas has been dispensed. It is believed that this feature increases the safety of the device since operators cannot replace or access the high pressure gas cartridge. Additionally because the device is disposable there is no servicing or maintenance of the CryOmega device.

CONCLUSION

In summary, the CryOmega's path through the 510(k) flowchart [1] is as follows:

- The CryOmega has the same intended use as the predicate cryogenic device that is intended for the destruction of tissue using nitrous oxide.
- The CryOmega has the same technological characteristics as the Cryoprobe-C Device which sprays liquid nitrous oxide gas.
- Both the CryOmega and Predicate using valves to dispense nitrous oxide gas. Therefore technological differences between the CryOmega and its predicate devices do not raise new questions of safety or efficacy.
- The 510(k) notice includes data and literature to verify that the nitrous oxide in the CryOmega device can safely and effectively cause destruction when used as instructed.

Therefore, STC Consulting believes that FDA can find the CryOmega to be substantially equivalent to the Cryoprobe-C device.

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[1] *FDA Guidance-Format for Traditional & Abbreviated 510k's 2005*

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

STC Consulting LLC
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Allentown, Pennsylvania 18103

OCT 6 2010

Re: K102006
Trade/Device Name: CryOmega™
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 03, 2010
Received: September 13, 2010

Dear Dr. Niedbala:

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,

Dep 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

510(k) Number (if known): K102006

Device Name: CryOmega ™

Indications For Use:

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-Genital Lesions
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-Verruca Vulgaris
-Verruca Plana
-Actinic Keratosis
-Lentigo

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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

510(k) Number K102006

Concurrence of CDRH, Office of Device Evaluation (ODE)