K050272

510(k) Summary

February 1st 2005

1 Submitter

MAR 2 4 2005

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2 Name of Device

Proprietary Name: Cryo-PaC™ systems, comprising:

a) Cryo-PaC™ console, Cryo-PaC™ Plus console, and Cryo-PaC™ Ultra console
b) Cryo-PaC™ 1.3 mm cryoprobe
d) Cryo-PaC™ 2.0 mm cryoprobe
e) Cryo-PaC™ 2.1 mm cryoprobe
f) Cryo-PaC™ 2.6 mm cryoprobe
g) Convenience procedure kit for probe placement

Common Name: Cryoanalgesia System

Device Classification: Cryogenic surgical devices have been placed in Class II as per 21 CFR Regulation Number 882.4250 and assigned the Product Code GXH

3 Predicate Devices

The components of the Cryo-PaC™ system are substantially equivalent to the following legally marketed devices:

K031482	Cryomedical Instruments CryoStar™
K781302	Spembly Lloyd Neurostat®
K854334	Wallach Painblocker WA5000

This statement is based on the similarity of the subject device to the predicate devices in intended use, materials, design and principles of operation.

4 Device Description

The Cryo-PaC™ systems comprise a choice of three versions of a cryoanalgesia console: the base model Cryo-PaC™, and the Cryo-PaC™ Plus and Cryo-PaC™ Ultra; all based on the same control module but providing a range of features for the control of the cryogen gas. The consoles are complemented by a range of cryoprobes that are used for freezing nerves to block pain by temporary ablation. The Cryo-PaC™ console is used to control the supply of gas to the cryoprobe and to provide an electrical nerve location device. A footswitch completes the system. A convenience procedure kit for probe placement is also provided as a single use disposable.

In the Cryo-PaC™ systems, compressed nitrous oxide or carbon dioxide is directed to the tip of the cryoprobe where it is allowed to expand through a fine annular space. The expansion of the gas to near atmospheric pressure causes cooling by the Joule Thompson effect. The design of the cryoprobes is such that the warmer incoming gas maintains the outer stem of the cryoprobe above freezing temperatures to prevent freezing up the stem of the cryoprobe and unwanted tissue damage. A peripheral nerve stimulator in the Cryo-PaC™ consoles facilitate the location of the peripheral nerve prior to freezing. Freezing of the nerve fibers creates a block which prevents the conduction of pain. The effect is usually non-permanent, and a repeat of the treatment may be necessary to deal with long term pain.

The Cryo-PaC™ consoles have been designed to provide a simple user interface, together with a series of error detection and warning systems to ensure proper operation. In the Cryo-PaC™ Plus and Ultra models the console includes a pedestal that provides a convenient small footprint mobile base for the system, and houses the gas tanks. A simple footswitch completes the system.

5 Intended Use

The Cryo-PaC™ systems are a series of cryoanalgesia devices intended for use in blocking pain by temporarily ablating the peripheral nerves.

6 Summary of Substantial Equivalence

The Cryo-PaC™ systems are similar in design, intended use and performance characteristics to the predicate devices. There are now new issues of safety of effectiveness raised by the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Mr. Gareth Copping
Technical Director
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NG19 8BW
United Kingdom

Re: K050272
Trade/Device Name: Cryomedical Instruments Cryo-PaC™ Systems
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic surgical device
Regulatory Class: II
Product Code: GXH
Dated: February 28, 2005
Received: March 1, 2005

Dear Mr. Copping:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 begin 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) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K050272

Device Name: Cryomedical Instruments Cryo-PaC™ Systems

Indications for Use: The Cryo-PaC™ systems are a series of cryoanalgesia devices intended for use in blocking pain by temporarily ablating the peripheral nerves.

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

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

Concurrence of CDRH Office of Device Evaluation (ODE)

K050272