K100447

MyoScience

JUN 25 2010

Section 5: 510(k) Summary

Device Information:

Category:	Comments:
Sponsor / Submitter:	MyoScience, Inc 525 Chesapeake Drive Redwood City, CA 94063 (650) 474-2600 (650) 474-2700
Correspondent Contact Information:	Tracey Henry Sr. Director RAQA, Clinical Compliance 525 Chesapeake Drive Redwood City, CA 94063 (650) 474-2600 (650) 474-2900
Device Common Name:	Cryogenic Surgical device
Device Classification & Code:	Class II, GXH
Device Classification Name:	Cryosurgical unit and accessories (21 CFR 882.4250)
Device Proprietary Name:	MyoScience Cryo-Touch

a. Predicate Device Information:

The Cryo-Touch is substantially equivalent to the following currently legally marked devices:

510(k) Number	Product	Sponsor
K083493	Cryo-Touch	MyoScience, Inc
K050272	Cryo-PaC™ System	Cryomedical Instruments
K854334	Painblocker WA 5000	Wallach Surgical Devices
K831963	Cryomedics Neurostat	Spembly Medical Ltd

b. Date Summary Prepared

June 21, 2010

c. Description of Device

The MyoScience Cryo-Touch is a hand-held, single patient-use disposable, cryogenic device used to destroy nervous tissue or produce lesions in peripheral nervous tissue by the application of cold to the selected site for the purposes of blocking pain. The Cryo-Touch has been developed for applications in cryoanalgesia. Cryoanalgesia for intractable pain involves the location and freezing of the nerve associated with the pain.

The device is based on introduction of a cryoprobe cooled by the cryogenic fluid (liquid nitrous oxide (N_2O)) to the selected site and activation of the freeze control. An iceball forms around the tip of the needle assembly and the adjacent nerve.

The Cryo-Touch may be used with a standard off-the-shelf nerve stimulator device in applications where precise nerve location is desired.

Device Design

The device is comprised of three main components:

1) a control unit (controller) with cryogen cap,
2) needle assembly (Cryoprobe), and
3) a cryogen cylinder(Nitrous Oxide).

The entire device is hand-held and for single patient-use.

The Cryo-Touch controller is battery operated; the battery powers electronics within the controller that control the nitrous oxide flow and regulate light emitting diodes (LEDs) that provide feedback to the user when the device is ready to use.

An assortment of needle assemblies is available for the Cryo-Touch, ranging from a single to a dual needle, from 25 gauge to 30 gauge, and from 10mm to 25 mm in length. All needle assemblies are made of stainless steel and have a closed-tip that fully contains the cryogen so that it does not enter the target tissue. The needle assembly is the only patient contacting component of the Cryo-Touch. The user removes the needle assembly from the sterile packaging and attaches it to the controller by inserting the needle hub end into the distal end of the controller.

The cryogen is provided as a nitrous oxide cylinder. The cartridge is filled with liquid N_2O (83%) and the rest with N_2O gas. A single nitrous oxide cylinder treats for approximately 180 seconds. The cylinder, once empty, may be replaced with a new cylinder by the user.

Device Functionality/Scientific Concepts

The device functionality is based on the user introducing the needle assembly proximate to the target nervous tissue. The user then initiates the flow of cryogen by opening the start/stop valve. Liquid cryogen flows from the controller into the closed-tip needle assembly. The needle is cooled by the Joule-Thompson effect; as the liquid cryogen expands into a gas, an iceball develops around the external surface of the needle assembly causing the surrounding tissue to be frozen. As the iceball grows, its leading edge advances through the tissue and tissue that comes into contact with the needle is frozen to a nominal target temperature of -65°C (-85°F). The user then stops the flow of cryogen by closing the start/stop valve and allows the iceball to thaw before removing the needle assembly.

d. Intended Use

The MyoScience Cryo-Touch is used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The Cryo-Touch is not indicated for treatment of central nervous system tissue.

e. Comparison to Predicate Devices

The MyoScience Cryo-Touch is substantially equivalent in intended use, technology, design and materials to the above listed legally marketed predicate devices. The technological characteristics of the new device in comparison to the predicate devices are summarized below:

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	This Device	Predicate Device			
Parameter	MyoScience Cryo-Touch	MyoScience Cryo-Touch K083493	Cryomedical Instruments Cryo-PaC™ System K050272	Wallach Surgical Devices Painblocker WA5000 K854334	Spembly Medical Ltd Cryomedics Neurostat K831963
Intended Use	Identical to all predicates	Destroy tissue through freezing			
Target Population	Identical to all predicates	Adults			
Anatomical Sites	Identical to predicates	Not specified	Peripheral nerves		
Intended users/clinical setting	Identical to all predicates	Qualified medical personnel (doctors, specialists) in hospital or medical environment			
Technology	Identical to Cryo-Touch. Similar to Cryo-Pac, Painblocker WA5000 and Neurostat.	Cryogenic surgical device with needle which penetrates treatment area.			
Energy used/or delivered	Identical to all predicates	Cryotherapy/ Nitrous Oxide	Cryotherapy/ Nitrous Oxide	Cryotherapy/ Nitrous Oxide or Carbon Dioxide	Cryotherapy/ Nitrous Oxide or Carbon Dioxide
Human Factors	Identical to Cryo-Touch.	Hand-held and or portable device containing cryogen. Some units have footswitch and detachable cryoprobes.			
Biocompatibility	Identical to all predicates	Biocompatible patient contacting materials			
Operating Principle	Identical to all predicates	Joule-Thomson Effect			
Patient contacting materials	Identical to Cryo-Touch	Closed-tip stainless steel cryoprobe Ranging from 12 – 30 gauge			
Treatment Temperature	Identical to Cryo-Pac, Painblocker WA5000 and Neurostat	-15° C to -25°C (5°F to -13°F) for Cryo-Touch, -55°C to -80 (-67°F to -112°F) for other predicates			
Power Source	Yes. Identical to Cryo-Touch	Battery powered	Mains powered	Battery powered	Battery powered

The device that is the subject of this 510(k) application is identical to the previously cleared Cryo-Touch device with the following exceptions:

(1) A proprietary filter was added internally. The filter has no direct or indirect patient contact.
(2) The Cryo-Touch now delivers a target treatment temperature of -65°C which is within the range of the other predicate devices, the Cryo-Pac, the Painblocker WA5000 and the Neurostat.

f. Summary of Supporting Data

Nonclinical testing Submitted: Verification testing was performed on the Cryo-Touch device to demonstrate that the product met the design requirements for system performance and temperature profiling during simulated use conditions.

	A preclinical animal study designed to evaluate the effects of cryo-treatment with the Cryo-Touch device on peripheral nerves in a rat model was performed. The study evaluated the impact of the cryolesioning treatment on peripheral nerves in terms of physiologic function and histologic changes. All other relevant performance testing was submitted as part of the submission for the predicate Cryo-Touch device.
Clinical Testing Submitted:	None

g. Conclusion

MyoScience concludes that the Cryo-Touch described in this submission 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

MyoScience, Inc.
c/o Ms. Tracey Henry
Sr. Director, Regulatory Affairs and Quality Assurance
525 Chesapeake Drive
Redwood City, CA 94063

JUN 2 5 2010

Re: K100447
Trade/Device Name: Cryogenic Surgical Device
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GXH
Dated: June 21, 2010
Received: June 22, 2010

Dear Ms. Henry:

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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation Health
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number:

K100447

Device Name:

MyoScience Cryo-Touch

Indications for Use:

The MyoScience Cryo-Touch is used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The Cryo-Touch is not indicated for treatment of central nervous system tissue.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daryl Kaufman

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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