510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

SEP 17 2010

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 II

a. Predicate Device Information:

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

510(k) Number	Product	Sponsor
K100447	Cryo-Touch	MyoScience, Inc

b. Date Summary Prepared

July 16, 2010

c. Description of Device

The MyoScience Cryo-Touch II 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 II 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 II may be used in conjunction 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),
2) probe assembly, and
3) a cryogen cylinder assembly (Nitrous Oxide).

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

The Cryo-Touch II 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 II, ranging from a single to a triple needle, from 25 gauge to 30 gauge, and from 6mm 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 II. 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 II 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 II is not indicated for treatment of central nervous system tissue.

e. Comparison to Predicate Devices

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

Parameter	This Device MyoScience Cryo-Touch II	Predicate Device MyoScience Cryo-Touch K100447
Intended Use	Identical	Destroy tissue through freezing
Target Population	Identical	Adults
Anatomical Sites	Identical	Peripheral nerves
Intended users/clinical setting	Identical	Qualified medical personnel (doctors, specialists) in hospital or medical environment
Technology	Identical	Cryogenic surgical device with needle which penetrates treatment area.
Energy used/or delivered	Identical	Cryotherapy/ Nitrous Oxide
Human Factors	Identical	Hand-held and or portable device containing cryogen. Some units have footswitch and detachable cryoprobes.
Biocompatibility	Identical	Biocompatible patient contacting materials
Operating Principle	Identical	Joule-Thomson Effect
Patient contacting materials	Identical	Closed-tip stainless steel cryoprobe Ranging from 25 – 30 gauge
Treatment Temperature	Identical	-55° C to -75°C
Power Source	Identical	Battery powered

f. Summary of Supporting Data

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

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

SEP 17 2010

Re: K102021
Trade/Device Name: Myoscience Cryo-touch II
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: II
Product Code: GXH
Dated: August 23, 2010
Received: August 24, 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,

Keria 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

Indications for Use Statment

510(k) Number:

Device Name:

SEP 17 2010

MyoScience Cryo-Touch II

Indications for Use:

The MyoScience Cryo-Touch II 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 II 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)

David L. Kaufman MA
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K102021