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 Director RAQA, Clinical Compliance 525 Chesapeake Drive Redwood City, CA 94063 (650) 474-2600 (650) 474-2900
Device Common Name:	Cryosurgical unit and accessories
Device Classification & Code:	Class II, GEH
Device Classification Name:	Cryosurgical unit and accessories (21 CFR 878.4350)
Device Proprietary Name:	MyoScience Cryo-Touch

a. Predicate Device Information:

- CryoProbe (K024009), H&O Equipments NV/SA, Inc
- CryoShape (K060928), Etgar Group H.M.Y.A. Ltd

b. Date Summary Prepared

March 17, 2009

c. Description of Device

The MyoScience Cryo-Touch device is a hand-held, single patient-use disposable, cryosurgical instrument used for destroying tissue by subcutaneous insertion of a needle during general surgical procedures. The device is based on introduction of a needle cooled by the cryogenic fluid (liquid nitrous oxide (N_2O)) to a selected area. The needle is cooled by the Joule-Thompson effect.

The Cryo-Touch comes with a variety of stainless steel closed-tip needle assemblies for use in various applications.

The Cryo-Touch uses a commercially available nitrous oxide cylinder.

d. Intended Use

The MyoScience Cryo-Touch device is intended to destroy tissue during surgical procedures by applying freezing cold.

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.

f. Summary of Supporting Data

Biocompatibility data demonstrates that the device is in compliance with ISO 10993.

Performance testing has demonstrated that the device is in compliance with pertinent standards, the medical community's expectations and the product labeling.

g. Conclusion

MyoScience concludes that the Cryo-Touch described in this submission is substantially equivalent to the predicate devices and no new issues of safety or efficacy have been introduced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MyoScience, Inc.
% Tracey Henry
Director RA/QA, Clinical Compliance
525 Chesapeake Drive
Redwood City, California 94063

MAR 2 0 2009

Re: K083493
Trade/Device Name: MyoScience Cryo-Touch
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: February 23, 2009
Received: February 25, 2009

Dear Tracey 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number:
K083493

Device Name:
MyoScience Cryo-Touch

Indications for Use:
The MyoScience Cryo-Touch device is intended to destroy tissue during surgical procedures by applying freezing cold.

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)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083493