DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 21, 2015

Myoscience, Inc
Tracey Henry
VP RAQA, Operations
1600 Seaport Blvd, North Lobby, Suite 450
Redwood City, California 94063-2

Re: K142866
Trade/Device Name: Myoscience Iovera System
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: Class II
Product Code: GXH
Dated: October 22, 2014
Received: October 23, 2014

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142866

Device Name
Myoscience iovera system

Indications for Use *(Describe)*
The myoscience iovera° system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The iovera° system is not indicated for treatment of central nervous system tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Information:

Category	Comments
Sponsor / Submitter:	Myoscience, Inc 1600 Seaport Blvd North Lobby, Suite 450 Redwood City, CA 94063 Ph: (650) 474-2600 Fax: (650) 474-2700
Correspondent Contact Information:	Tracey Henry Vice President RAQA, Operations 1600 Seaport Blvd North Lobby, Suite 450 Redwood City, CA 94063 Ph: (650) 474-2600 Fax: (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 Trade Name:	Myoscience iovera° system

a. Predicate Device Information:

510(k) Number	Product	Sponsor
K133453	iovera°	Myoscience, Inc

This predicate has not been subject to a design-related recall.

b. Date Summary Prepared

September 30, 2014

c. Description of Device

The iovera° system is a portable cryogenic surgical device used to destroy tissue and/or produce lesions in nervous tissue through application of extreme cold to the selected site. The device is based on introduction of a Smart Tip internally cooled by the cryogenic fluid (nitrous oxide, N_2O) to a selected area. The Smart Tip is cooled by the Joule-Thomson Effect and/or Latent Heat of Vaporization. iovera° 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 four main components:

1. A reusable Handpiece
2. A Charging Dock
3. An assortment of single-patient use Smart Tips
4. A Cartridge (Nitrous Oxide)

The iovera° Handpiece is battery powered (single cell Lithium Ion, 3.7 volts) and provides feedback to the user during device preparation and use. The Handpiece connects to both the Cartridge and to the Smart Tip. The user activates a treatment cycle through a control on the Handpiece, which starts and stops the treatment. The Handpiece also contains LEDs for providing feedback to the user when the device is ready

to use. The Charging Dock stores the Handpiece between uses and provides power for charging the battery.

An assortment of Smart Tips is available for the iovera° system. All Smart Tip needles are made of stainless steel and have a closed-end that fully contains the cryogen so that it does not enter the target tissue. The Smart Tip is the only patient contacting component of the iovera° system. The user removes the Smart Tip from the sterile packaging and attaches it to the Handpiece.

The iovera° system uses a commercially available nitrous oxide cylinder. The Cartridge is filled with pure N_2O.

Device Functionality/Scientific Concepts

The device functionality is based on the user introducing the Smart Tip to the selected treatment area: unwanted tissue or the target nervous tissue. The user then initiates the flow of cryogen by pressing the on/off button. Liquid cryogen flows from the Handpiece into the closed-end Smart Tip. The Smart Tip is cooled by the Joule-Thomson Effect and/or Latent Heat of Vaporization; as the liquid cryogen expands into a gas, the temperature drops around the external surface of the Smart Tip causing the surrounding tissue to freeze. The treatment is completed after a pre-programmed amount of time at which time the user can safely remove the Smart Tip.

d. Indications for Use

The myoscience iovera° device is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The iovera° device is not indicated for treatment of central nervous system tissue.

The Indications for Use statements for the subject and predicate devices are identical.

e. Comparison of Technological Characteristics with the Predicate Device

Following are the similarities/differences in technological characteristics between the subject and predicate devices. The differences in technological characteristics do not raise different questions of safety and effectiveness for the subject device as compared to the predicate device.

Technological Characteristics	
Predicate Device (K133453)	**Subject Device**
Cryogenic device	Same
Nitrous oxide coolant, pressurized cylinder	Same
Reusable handpiece, battery powered	Same
Single use tip for subdermal cooling, EO sterilized	Same
Charging dock	Same
Sensors, monitor nitrous oxide deliver and rate of cooling	Same
Smart Tip Needle • Length: 6 – 25mm (0.2 – 1.0in) • Size: Ø.31 – .52mm (25 – 30 gauge) • Patient contacting materials: Closed sharp cutting tip Stainless Steel needle	Smart Tip Needle • Length: 6 – 55mm (0.2 – 2.2in) • Size: Ø.31 – .72mm (22 – 30 gauge) • Patient contacting materials: Closed sharp cutting and blunt tip Stainless Steel needle Single Smart Tip configurations from 10 mm to 55 mm contain

	electrochemically etched markings on the needle surface

f. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing: The biocompatibility evaluation for the Smart Tip needle was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'"and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization (supplier testing)
- Intracutaneous reactivity (supplier testing)

The stainless steel Smart Tip needle is considered tissue contacting for a duration of less than 24 hours.

Software testing: Software verification testing was conducted and documentation was provided as recommended by FDA's Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent design flaw in the software could directly result in minor injury to the patient or operator. Specifically, the following test was performed:

Test Performed	**Result**
Tip Descriptor verification to confirm treatment parameters	PASS

Bench testing: Bench testing was performed on the new Smart Tip to demonstrate that the product met the design requirements. A risk analysis was used to assess the impact of the modification, as well, and design verification testing was performed as a result of this risk analysis assessment. In all cases, the risk was mitigated to acceptable levels and the performance testing demonstrated that the device is in compliance with pertinent standards (i.e., ISO 11135-1). Needle integrity validation test was modified from the predicate to demonstrate safety and effectiveness due to the changes in needle design and longer length. Specifically, the following tests were performed:

Test Performed	**Result**
Visual and dimensional inspection of Smart Tip needle	PASS
Verification of temperature reproducibility	PASS
Validation of cryozone size	PASS
Validation of needle integrity in simulated use conditions	PASS

• After flexing, needle shall return to straight condition • Needle shall not leak after kink failure	
Sterility Testing	PASS
Transit/Shelf Life Testing	PASS

Preclinical Testing Submitted: No preclinical testing was deemed necessary for this modification.

Clinical Testing Submitted: No clinical testing was deemed necessary for this modification.

g. Conclusion

The performance data demonstrate that the iovera° system is as safe, as effective, and performs comparably to the predicate device that is currently marketed for the same intended use.