February 28, 2018

Myoscience, Inc.
Kent Jones
Senior Director, RAQACA
46400 Fremont Blvd
Fremont, California 94538

Re: K173763
Trade/Device Name: iovera° system
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: Class II
Product Code: GXH, ETN
Dated: December 7, 2017
Received: December 11, 2017

Dear Kent Jones:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173763

Device Name
iovera° system

Indications for Use *(Describe)*
The 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. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. The iovera° system is not indicated for treatment of central nervous system tissue.

The iovera° system's "1x90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator.

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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myoscience

Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor / Submitter:	Myoscience, Inc 46400 Fremont Blvd Fremont, CA 94538 Ph: 510.933.1500 Fax: 410.933.1501
Correspondent Contact Information:	Kent Jones Sr. Director RAQACA, Myoscience, Inc Telephone: 510.933.1513 Email: kjones@myoscience.com
Device Common Name:	Cryogenic surgical device
Device Classification & Code:	Class II, GXH, ETN
Device Classification Name:	Cryosurgical unit and accessories (21 CFR 882.4250), Surgical nerve stimulator (21 CFR 874.1820)
Device Trade Name:	iovera° system

a. Predicate Device Information:

510(k) Number	Product	Sponsor
K161835	iovera° system	Myoscience, Inc
K100241	B Braun Stimuplex D Insulated Needle	B Braun Medical, Inc

b. Date Summary Prepared

7 December 2017

c. Description of Device

The iovera° system is a portable cryogenic surgical device used to destroy tissue and/or produce lesions in nervous tissue creating a nerve block 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. The iovera° system 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 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 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. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. The system's "1x90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator. The iovera° system is not indicated for treatment of central nervous system tissue.

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 (K142866)	**Subject Device** 1x90 Smart Tip
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 range • Length: 6 – 55mm (0.2 – 2.2 in) • Size: Ø.31 – .72mm (25 – 30 gauge) • Patient contacting materials:	Smart Tip Needle • Length: 90mm (3.5 in) • Size: Ø.91mm (20 gauge) • Patient contacting materials:

Closed sharp cutting and blunt tip Stainless Steel needle	Closed sharp cutting Stainless Steel needle with Parylene C coating • Includes electrical nerve stimulation capability (using off-the-shelf nerve stimulator)

Technological Characteristics	
Predicate Device (K100241) B Braun Stimuplex D Insulated Needle	Subject Device 1x90 Smart Tip
Single use needle	Same
Electrical nerve stimulation capability (using Stimuplex nerve stimulator)	Same
Needle range • Length: 35 – 120mm (1-3/8 in – 4-3/8 in) • Size: Ø.91 – .51mm (20 – 25 gauge) • Patient contacting materials: Open sharp cutting Stainless Steel needle with clear dielectric coating.	Smart Tip Needle • Length: 90mm (3.5 in) • Size: Ø.91mm (20 gauge) • Patient contacting materials: Closed sharp cutting Stainless Steel needle with Parylene C coating

f. Performance Data

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

Biocompatibility Testing	Biocompatibility testing was conducted on the new Smart Tip needle in accordance with ISO-10993, 'Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing" as recognized by FDA. The battery of testing included the following test: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute System Toxicity • Material-Mediated Pyrogenicity
Software Testing	Software verification testing for the new Smart Tip descriptor was conducted as recommended by FDA's Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" in conjunction with bench testing of the Smart Tip (see below). No other software changes were required for this submission.
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 Smart Tip design is in compliance with pertinent standards. Specifically, the following tests were performed:

Test Performed	Result
Electrical Safety Testing per IEC 60601-1	PASS
EMC/Immunity Testing per IEC 60601-1-2	PASS
Visual and Dimensional Inspection of Smart Tip needle	PASS
Verification of temperature reproducibility	PASS
Cryozone Testing	PASS
Needle Integrity	PASS
Tip Descriptor verification to confirm treatment parameters	PASS

Preclinical Testing Submitted: No preclinical testing was deemed necessary for the product line extension

Clinical Testing Submitted: No clinical testing was deemed necessary for the product line extension.

g. Conclusion

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