

510(k) Summary

Device Information:

| Category | Comments |
|--|---|
| Sponsor / Submitter: | myoscience, Inc. 1600 Seaport Blvd. North Lobby, Suite 450 Redwood City, CA 94063 (650) 474-2600 (650) 474-2700 |
| Correspondent Contact Information: | Bijesh Chandran Director Regulatory Affairs and Quality Assurance 1600 Seaport Blvd. North Lobby, Suite 450 Redwood City, CA 94063 (650) 421-2110 (650) 474-2900 |
| Device Common Name: | Cryogenic Surgical Device |
| Device Classification & Code: | Class II, GXH |
| Device Classification Name & Regulation: | Cryosurgical unit and accessories (21 CFR 882.4250) |
| Device Proprietary Name: | iovera ^o |

a. Predicate Device Information:

The iovera^o device is substantially equivalent to the following currently legally marketed devices:

| 510(k) Number | Product | Sponsor |
|---------------|---------------|-----------------|
| K123516 | Cryo-Touch IV | myoscience, Inc |

b. Date Summary Prepared

November 07, 2013

c. Description of Device

The myoscience iovera^o device 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, N₂O) to a selected area. The Smart Tip has the added functionality of having the treatment parameters being pre-programmed into its secure processor. The Smart Tip is cooled by the Joule-Thomson Effect and/or Latent Heat of Vaporization. The iovera^o device 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. A single-patient use Smart Tip
4. A Cartridge (Nitrous Oxide)

The iovera^o 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^o device. All Smart Tips 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^o device. The user removes the Smart Tip from the sterile packaging and attaches it to the Handpiece.

The iovera^o device uses a commercially available nitrous oxide cylinder (N₂O). The Cartridge is filled with pure N₂O.

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. Intended Use

The myoscience iovera^o 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^o device is not indicated for treatment of central nervous system tissue.

e. Comparison to Predicate Devices

The myoscience iovera^o device is substantially equivalent in intended use, technology, design and materials to the above listed legally marketed predicate device.

f. Summary of Supporting Data

Nonclinical testing: Verification testing was performed on the myoscience iovera^o device to demonstrate that the product met the design requirements for system performance. These specific tests are listed below.

| Test Performed | Result |
|---------------------------------|---|
| Temperature reproducibility | PASS, Substantially equivalent to predicate |
| Mechanical Integrity for System | PASS, Substantially equivalent to predicate |
| Nitrous Exposure | PASS, Substantially equivalent to predicate |
| Cryozone Size | PASS, Substantially equivalent to predicate |

| Test Performed | Result |
|--------------------------------------|---|
| Needle Integrity | PASS, Substantially equivalent to predicate |
| Sterilization and Shelf Life Testing | PASS, Substantially equivalent to predicate |
| Electrical Safety Testing | PASS, Substantially equivalent to predicate |
| Software Testing | PASS, Substantially equivalent to predicate |
| Safety Testing | PASS, Substantially equivalent to predicate |
| Biocompatibility Testing | PASS, Substantially equivalent to predicate |

This performance testing demonstrated that the device is in compliance with pertinent standards (IEC 60601-1, IEC 60601-1-2, ISO 10993-1 and ISO 11135-1), the product labeling, and is substantially equivalent to the predicate.

Clinical Testing Submitted: None

g. Conclusion

myoscience concludes that the iovera^o device described in this submission is substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

Myoscience, Inc.
c/o Mr. Bijesh Chandran
Director of Regulatory Affairs and Quality Assurance
1600 Seaport Blvd., North Lobby
Suite 450
Redwood City, California 94063

Re: K133453

Trade/Device Name: iovera[®]
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GXH
Dated: February 18, 2014
Received: February 20, 2014

Dear Mr. Chandran:

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 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>. 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 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,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K133453

Device Name
iovera[®]

Indications for Use (Describe)

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joyce M. Whang -S

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

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