September 10, 2021

Pacira Pharmaceuticals Inc.
Kent Jones
Senior Director QA/RA
46400 Fremont Blvd
Fremont, California 94538

Re: K211334
Trade/Device Name: Iovera System
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: Class II
Product Code: GXH
Dated: August 10, 2021
Received: August 11, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211334

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

a. Date Summary Prepared:

Date: 09/10/2021

510(k) Type:	Special
Name of Device:	iovera° System
Device Class:	Class II
Product Code:	GXH-Cryogenic Surgical device
Regulation:	21 CFR Part 882.4250
Sponsor/Submitter:	Pacira Pharmaceuticals, Inc. 46400 Fremont Blvd Fremont, CA 94538 Ph: 510-933-1500 Fax: 510-933-1501
Establishment Registration:	3009131456
Correspondent Contact Information:	Kent Jones, Senior Director QA/RA Pacira Pharmaceuticals Inc. Email: kent.jones@pacira.com Ph: 510-933-1513

b. Predicate Device Information:

The iovera° system is substantially equivalent to the following currently legally marketed device:

510(k) Number	Product	Sponsor
K161835	iovera° system	Pacira Pharmaceuticals

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.

Device Design

The device comprises four main components:

- A reusable Handpiece
- A Charging Dock
- An assortment of single-patient-use Smart Tips
- A Cartridge containing 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 contains an LCD display 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 design 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 its sterile packaging and attaches it to the Handpiece immediately before use.

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 into the selected treatment area 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 from the treatment site.

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 iovera° system is not indicated for treatment of central nervous system tissue.

e. Technological Characteristics Comparison to Predicate Device:

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

Technological Characteristics	
Predicate Device	**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 delivery	Same

f. Performance Data:

Design Verification testing was performed for the iovera° system to demonstrate that the device meets product specifications. Using a risk-based approach for the modifications, design verification testing was performed according to recognized standards, and is consistent with the predicate device and test methods described in previous 510(k) submissions for the iovera° system. The verification methods used and applied are appropriate for the changes. The verification and validation testing assures the modified subject device meet design input requirements, product specifications and relevant standards.

Verification and validation performed on the subject device supports the substantial equivalence of the modified iovera° system to the predicate device:

- Functional Testing
- Product Performance (Handpiece and Cartridge)
- Smart Tip Testing
- User Interface Testing
- Electrical /EMC safety Testing

The subject iovera° system device met the design verification and validation inputs, passing all predetermined acceptance criteria. No new issues of safety or effectiveness were identified during design verification and validation testing.

g. Conclusion:

The subject iovera° system, with the same intended use, indications for use, design, materials, technological features, and principles of operation as the cleared iovera° system (K161835), is substantially equivalent to the predicate device. The modification proposed in this 510(k) does not affect the safety and effectiveness of the device as the intended therapeutic use for the creation of lesions with the application of cold in peripheral nerves to block pain has not changed.

The modifications described, and the data presented, in this special premarket notification demonstrates that iovera° system is safe and effective, does not introduce or raise new questions of safety and effectiveness, and is substantially equivalent in intended use, technology, design, and materials to the legally marketed predicate device.