Ivenix, Inc.
John Sokolowski
VP, Regulatory Affairs
50 High St
North Andover, Massachusetts 01845

Re: K213089
Trade/Device Name: Ivenix Infusion System, LVP Epidural Administraion Set NRFit Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: October 7, 2021
Received: October 8, 2021

Dear John Sokolowski:

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); 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,

Carolyn Dorgan
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K213089

Device Name
Ivenix LVP Epidural Administration Set with NRFit Connector

Indications for Use *(Describe)*

The Ivenix LVP Epidural Administration Set with NRFit Connector (SET-0030-1) is intended for the controlled administration of pharmaceutical drugs or other patient therapies via the epidural pathway. The Ivenix LVP Epidural Administration Set is intended only for use with the Ivenix Infusion System in a hospital or outpatient care environment.

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.

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510(K) SUMMARY
K213089

Manufacturer's Name:	Ivenix, Inc. 50 High Street, North Andover, MA 01845
Corresponding Official:	John J. Sokolowski Vice President, Regulatory Affairs
Telephone Number:	(978) 775-8050
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E-mail Address:	john.sokolowski@ivenix.com
Trade Name:	Ivenix LVP Epidural Administration Set with NRFit Connector, SET-0030-1
Common or Usual Name:	Epidural infusion administration set
Regulation Name:	Set, administration, intravascular
Regulation Number:	21 CFR 880.5440
Product Codes:	FPA
Device Class:	Class II
Predicate Device:	K183311 Ivenix Infusion System, Epidural Administration set with luer connector (SET-0016-1)

Device Description

The Ivenix LVP Epidural Administration Set with NRFit connector is comprised of a primary channel inlet tubing with a vented cap spike, a cassette which contains the fluid pumping mechanism and serves as the interface to the Ivenix LVP, and outlet tubing for connection to patient access. The end of the outlet tubing is fitted with a NRFit connector that is compliant to ISO 80369-6:2013.

The Ivenix LVP Epidural Administration Set with NRFit Connector provides a sterile fluid path for the delivery of pharmaceutical drugs and other therapies via the epidural pathway, provides a means for a clinician to aseptically connect to the fluid source and to the patient access site, and interfaces with the LVP to enable measurement and control of the fluid delivery.

The Ivenix LVP Epidural Administration Set with NRFit Connector is intended for use within the Ivenix Infusion System for controlled fluid delivery; it is not recommended for gravity infusion.

Indications for Use

The Ivenix LVP Epidural Administration Set with NRFit Connector (SET-0030-1) is intended for the controlled administration of pharmaceutical drugs or other patient therapies via the epidural pathway. The Ivenix LVP Epidural Administration Set is intended only for use with the Ivenix Infusion System in a hospital or outpatient care environment.

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a comparison of the intended use between the subject device and those of the predicate device:

Characteristic	Subject Device Ivenix Infusion System, Microbore single inlet, single outlet, for administration of epidural fluids with NRFit® Connector (SET-0030-1)	Predicate Device Ivenix Infusion System K183311, Microbore single inlet, single outlet, for administration of epidural fluids with luer connector (SET-0016-1)	Discussion
Indications for Use	The Ivenix Infusion System is indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration: intravenous, intra-arterial, epidural, and subcutaneous to adults, pediatric and neonate patients. Administered fluids may be pharmaceutical drugs, red blood cells, platelets, plasma, and other mixtures required for patient therapy.	The Ivenix Infusion System is indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration: intravenous, intra-arterial, epidural, and subcutaneous to adults, pediatric and neonate patients. Administered fluids may be pharmaceutical drugs, red blood cells, platelets, plasma, and other mixtures required for patient therapy.	No differences between the devices.
Prescription Only or Over the Counter	Prescription Only	Prescription Only	No differences between the devices.
Intended Population	Adult, pediatric, neonate	Adult, pediatric, neonate	No differences between the devices.
Environment of Use	Hospital or out-patient setting	Hospital or out-patient setting	No differences between the devices.

Discussions of differences in Indications for Use statement
The indications for use statements are identical for both subject and predicate devices.

Discussions of differences in intended population
The intended population for the subject device is identical to the predicate device.

Discussions of differences in environment of use
There are no differences in the environment of use.

Technological Characteristics

The Ivenix LVP Epidural Administration Set with NRFit Connector is a modification of the Ivenix LVP Epidural Administration Set with Luer Connector (SET-0016-1). These sets have equivalent technological characteristics, as described below, and support substantial equivalence.

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Item	**Subject Device - Epidural Administration Set with NRFit connector (SET-0030-1)**	**Predicate Device - Epidural Administration Set with luer connector (SET-0016-1)**	**Discussion**
Single inlet	Primary line with vented spike and cap, no secondary inlet.	Primary line with vented spike and cap, no secondary inlet.	No differences between the devices.
Flow dial/regulator	The Flow Dial integrates with the LVP to maintain flow accuracy.	The Flow Dial integrates with the LVP to maintain flow accuracy.	No differences between the devices.
Connector	The connector that attaches the downstream outlet tubing to the patient access device has an NRFit connector, complaint to ISO 80369-6:2016 with cap.	The connector that attaches the distal line to the patient access device has a luer lock with cap.	The subject device has a connector that meets the requirements of a small bore connector, per ISO 80369-6:2016
Outlet Tubing / Distal Line (Patient Line)	Runs from the cassette to the patient.	Runs from the cassette to the patient.	No differences between the devices.
Upstream tubing	PE lined PVC with yellow stripe, length 29 +/- 1 in.	PE lined PVC with yellow stripe, length 29 +/- 1 in.	No differences between the devices

Item	Subject Device - Epidural Administration Set with NRFit connector (SET-0030-1)	Predicate Device - Epidural Administration Set with luer connector (SET-0016-1)	Discussion
Downstream tubing	PE lined PVC with yellow stripe, length 73 +/- 2 in.	PE lined PVC with yellow stripe, length 73 +/- 2 in.	No differences between the devices
Priming volume	10 mL	10 mL	No differences between the devices
Patient access connector materials of construction	Terlux 2802 ABS	Terlux 2802 ABS	No differences between the devices

Discussions of differences in technological characteristics

The technological characteristics of the subject and predicate devices are identical except for the dimensional characteristics of the patient access connector. The subject device meets the dimensional specifications of ISO 80369-6:2016.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device:

Conformance to ISO 80369-6:2013	The NRFit connector was tested against the requirements of ISO-80369-6:2016, using the methods described in ISO-80369-20:2015, by an accredited test laboratory. All requirements were met.
Connector bond strength	The epidural administration set with NRFit met the pull strength requirements of ISO 8536-4:2019.
Flow accuracy and shelf life testing	The epidural administration set with NRFit connector met all functional requirements of the Ivenix epidural set with luer connector.
Microbial Ingress	The sterile fluid path of the administration set was challenged, under simulated worst case conditions, at the patient access device, with four strains of bacteria (2 gram positive, 2 gram negative). Test results showed no growth of microorganism in any test article, demonstrating the integrity of the NRFit connector to maintain he sterile fluid path under simulated conditions of use.
Biocompatibility	The polymer material of the NRFit connector is identical to the standard luer connector of the predicate device in its final finished form in formulation, processing, sterilization, and geometry (with the exception of the geometry necessary to meet the requirements of ISO 80369-6:2016), and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). Therefore, no additional biocompatibility testing was conducted.

Clinical Tests

Clinical evaluation is not required for this submission to support substantial equivalence. Similarly, the predicate devices did not undergo clinical evaluation to support substantial equivalence.

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.