June 3, 2026

Deka Research and Development
Paul Smolenski
Regulatory Affairs
340 Commercial St.
Manchester, New Hampshire 03101

Re: K261530
Trade/Device Name: iiSure Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: May 7, 2026
Received: May 8, 2026

Dear Paul Smolenski:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JOSHUA BALSAM -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261530

Please provide the device trade name(s).

iiSure Infusion Set

Please provide your Indications for Use below.

The iiSure Infusion Set is indicated for the subcutaneous infusion of insulin, administered by an external pump. The infusion set is indicated for use with adult and pediatric users weighing greater than 10 kg. The infusion set is indicated for single-use.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary for K261530

This 510(k) Summary of safety and effectiveness information is prepared in accordance with the requirements of CFR Part 807.92.

Submitter Information

510(k) Sponsor	DEKA Research and Development 340 Commercial Street Manchester NH, 03101
Contact Person(s)	Paul Smolenski (primary), Jessica D Smith (secondary) Regulatory Affairs Phone: (603) 669-5139 Fax: (603) 624-0573 Email: psmolenski@dekaresearch.com, jesmith@dekaresearch.com
Date Prepared	June 01, 2026

Proposed Device(s)

Common/Usual Name:	Subcutaneous Infusion Set
Trade/Proprietary Name:	iiSure Infusion Set
Classification Name:	Set, Administration, Intravascular
Device Classification:	880.5440
Product Code:	FPA
Class:	II
Device Panel:	General Hospital

Predicate Device(s)

The subject device is a modified version of the predicate Sparta Insulin Infusion Set, cleared under K243841 on August 1, 2025. The subject device is substantially equivalent to the predicate Sparta Insulin Infusion Set.

Device Description

The Subject Device is a modified version of the predicate Sparta Insulin Infusion Set, with the following design changes and modifications:

- Rebranding from the previously named Sparta Insulin Infusion Set to iiSure Infusion Set.

- Including an additional configuration with a 3.5 inch tubing length.
- Increasing the maximum duration of wear to 96 hours.
- Increasing the shelf life to 2 years.
- Minor simplifications of the manufacturing process.

iiSure Infusion Set

The iiSure Infusion Set is a sterile, single-use, subcutaneous infusion set that establishes a sealed fluid path from an external portable infusion pump to the patient. Fluid is delivered to the patient through a 6 mm, 90°, soft cannula inserted in the subcutaneous tissue. The cannula is inserted using the preloaded, single-use mechanical Inserter. The infusion set has both 23 inch tubing length and 3.5 inch tubing length configurations that terminate in a Luer connecter.

Indications for Use

The iiSure Infusion Set is indicated for the subcutaneous infusion of insulin, administered by an external pump. The infusion set is indicated for use with adult and pediatric users weighing greater than 10 kg. The infusion set is indicated for single-use.

Substantial Equivalence Discussion

The table below compares the characteristics of the subject device to the predicate device.

Characteristic	**Predicate Device – K243841**	**Subject Device**	**Equivalence**
General			
Device Classification Regulation and Product Code	21 CFR 880.5440 Product Code: FPA	21 CFR 880.5440 Product Code: FPA	No Change.
Class	II	II	No Change.
Regulation Name	Intravascular Administration Set	Intravascular Administration Set	No Change.
Intended Use	The Sparta Infusion Set is indicated for the subcutaneous infusion of insulin, administered by an external pump. The infusion set is indicated for use with adult and pediatric users weighing greater than 10 kg. The infusion set is indicated for single-use.	The iiSure Infusion Set is indicated for the subcutaneous infusion of insulin, administered by an external pump. The infusion set is indicated for use with adult and pediatric users weighing greater than 10 kg. The infusion set is indicated for single-use.	Same. Branding has been updated to reflect the revised commercial product name.

Characteristic	**Predicate Device – K243841**	**Subject Device**	**Equivalence**
Prescription or Over the Counter (OTC)	Prescription	Prescription	No Change.
Intended Patient Population	Adult and pediatric users weighing greater than 10 kg.	Adult and pediatric users weighing greater than 10 kg.	No Change.
Description	Infusion set that consists of an infusion site, pre-loaded into a single-use inserter, and a tubing set that connects the infusion site to an external pump.	Infusion set that consists of an infusion site, pre-loaded into a single-use inserter, and a tubing set that connects the infusion site to an external pump.	No Change.
Physical Characteristics			
Inserter action	Subcutaneous insertion of soft cannula by introducer needle positioned inside the cannula during insertion.	Subcutaneous insertion of soft cannula by introducer needle positioned inside the cannula during insertion.	No Change.
Loading of infusion site into Inserter	Inserter is preloaded with infusion site.	Inserter is preloaded with infusion site.	No Change.
Needle safety	Automatic needle retraction after cannula insertion. Inserter needle not accessible after cannula insertion.	Automatic needle retraction after cannula insertion. Inserter needle not accessible after cannula insertion.	No Change.
Inserter lock	Inserter lock prevents inserter activation until removed.	Inserter lock prevents inserter activation until removed.	No Change.
Inserter operation	Cannula insertion in 4 steps: • Remove adhesive liner • Position inserter onto skin • Remove inserter lock Remove inserter from body and discard	Cannula insertion in 4 steps: • Remove adhesive liner • Position inserter onto skin • Remove inserter lock Remove inserter from body and discard	No Change.
Cannula insertion angle	90°	90°	No Change.

Characteristic	**Predicate Device – K243841**	**Subject Device**	**Equivalence**
Cannula length	6 mm	6 mm	No Change.
Cannula material	Polypropylene	Polypropylene	No Change.
Tubing Transparency	Transparent tubing	Transparent tubing	No Change.
Tubing Length	23 inch (58.4 cm)	23 inch (58.4 cm), **3.5 in (8.89 cm)**	Substantially Equivalent. The Subject Device has an additional 3.5" configuration. This shorter configuration has the same intended use, the same technological characteristics, and does not introduce any new questions of safety or effectiveness.
Connection to external infusion pump	Infusion Set attaches to pump via standard Luer lock connection.	Infusion Set attaches to pump via standard Luer lock connection.	No Change.
Tubing set disconnection/ reconnection	Tubing set can be disconnected from and reconnected to infusion site.	Tubing set can be disconnected from and reconnected to infusion site.	No Change.
Infusion Site Skin Adhesive	Non-woven adhesive	Non-woven adhesive	No Change.
Anatomical Location	Abdomen, upper leg, upper buttocks, hips, upper arms and lower back.	Abdomen, upper leg, upper buttocks, hips, upper arms and lower back.	No Change.
Biocompatibility			
Sterilization Method	EO	EO	No Change.
Sterility Assurance Level	10^{-6}	10^{-6}	No Change.

Characteristic	Predicate Device – K243841	Subject Device	Equivalence
Single Use	Yes (Infusion set and inserter)	Yes (Infusion set and inserter)	No Change.
Duration of Use	Up to 72 hours	**Up to 96 hours**	Substantially Equivalent. The insulin compatibility testing demonstrates insulin compatibility over a 96 hour duration of use with sufficient margin.
Disposal	Disposal in sharps/biohazard containers according to local regulations.	Disposal in sharps/biohazard containers according to local regulations.	No Change.
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	No Change.
Shelf life	1 year	**2 years**	Substantially Equivalent. Sterile barrier and device functional testing of aged samples demonstrates acceptable results at a 2 year shelf life.

Performance and Compatibility data

Insulin compatibility testing demonstrates compatibility over a 96 hour duration of use.

Sterility and Shelf Life

Performance testing was conducted on functionalities impacted by the extended shelf life of the subject device. The following areas of the system were tested.

- Shipping and Storage
- Sterile Barrier
- Device performance

Animal and Clinical Studies

No animal study or clinical trial data was required to support the Subject Device's indication for use or a substantial equivalence determination.

Design Control

The iiSure Infusion Set was specified and developed by DEKA. DEKA complies with the FDA Quality System Regulation as specified in 21 CFR 820, as well as ISO 13485:2016.

Conclusion

The differences between the Predicate and the Subject Devices does not raise any new or different questions of safety or effectiveness. The Subject Device is substantially equivalent to the Sparta Insulin Infusion Set cleared under K243841 with respect to the indications for use, treatment method, and technological characteristics.