August 1, 2025

DEKA Research and Development
Paul Smolenski
Regulatory Affairs
340 Commercial Street
Manchester, New Hampshire 03101

Re: K243841
Trade/Device Name: Sparta Infusion Set for Insulin
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: December 13, 2024
Received: December 13, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243841

Device Name
Sparta Infusion Set for Insulin

Indications for Use *(Describe)*
The Sparta Infusion Set for Insulin 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.

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."

DEKA Research & Development Corp.

510(k) Summary for K243841

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

1 Submitter

Name:	DEKA Research and Development, Corp. 340 Commercial Street Manchester, NH 03101 USA
Primary Contact:	Paul Smolenski Regulatory Affairs DEKA Research & Development Corporation Phone: 603-669-5139 Fax: 603-624-0573 psmolenski@dekaresearch.com
Alternate Contact:	William Calhoun Regulatory Affairs DEKA Research & Development Corporation wcalhoun@dekaresearch.com
Date Prepared:	July 28, 2025

2 Device

Trade Name:	Sparta Infusion Set for Insulin
Common Name:	Subcutaneous infusion set
Classification Regulation:	21 CFR § 880.5440 – Intravascular Administration Set
Product Codes:	FPA
Regulatory Class:	Class II

3 Predicate Device

The Predicate Device for which Substantial Equivalence is claimed is the Unomedical MiniMed Mio Advance infusion set cleared under K173879, cleared on 3/5/2018.

4 Device Description

The Sparta 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 a 23-inch tubing length that terminates in a Luer connecter.

5 Indications for Use

The Sparta Infusion Set for Insulin 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.

6 Substantial Equivalence Discussion

A comparison of the Subject and Predicate Devices with respect to indications for use, operating principles, and technological characteristics is provided in following table. Both devices have the same intended use and share the same fundamental operating principle. The minor differences in technological characteristics do not raise new questions of safety or efficacy.

Characteristic	**Sparta Infusion Set (Subject Device, K243841)**	**Unomedical MiniMed Mio Advance infusion set (Predicate Device, K173879)**	**Comparison**
Product Code	FPA	FPA	Same
Regulation Number	880.5440	880.5440	Same
Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
Intended Use	Intended for the subcutaneous delivery of insulin.	Intended for the subcutaneous delivery of insulin.	Same
Indications for Use	The Sparta Infusion Set for Insulin 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 MiniMed Mio Advance infusion set is indicated for subcutaneous infusion of medication administered by an external pump.	Substantially Equivalent. Subject Device's user population is covered by Predicate Device's user population.
Prescription Use	Yes	Yes	Same

Characteristic	Sparta Infusion Set (Subject Device, K243841)	Unomedical MiniMed Mio Advance infusion set (Predicate Device, K173879)	Comparison
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.	Same
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.	Same
Loading of infusion site into Inserter	Inserter is preloaded with infusion site.	Inserter is preloaded with infusion site.	Same
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.	Same
Inserter lock	Inserter lock prevents inserter activation until removed.	Inserter lock prevents inserter activation until removed.	Same
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 5 steps: • Remove adhesive liner • Remove inserter lock • Position inserter onto skin • Press/activate inserter • Remove inserter from body and discard	Substantially equivalent. Subject device has one less step, with all others being equivalent to Predicate device. Human factors validation testing demonstrated Subject Device could be operated safely and effectively.
Cannula insertion angle	90°	90°	Same
Cannula length	6 mm	6mm, 9mm	Same. Both devices contain 6 mm cannula.
Cannula material	Polypropylene	Polytetrafluoroethylene (PTFE)	Substantially equivalent. Both devices use a biocompatible cannula.

Characteristic	Sparta Infusion Set (Subject Device, K243841)	Unomedical MiniMed Mio Advance infusion set (Predicate Device, K173879)	Comparison
Tubing Transparency	Transparent tubing	Transparent tubing	Same
Tubing Length	23 inch (58.4 cm)	46 cm, 60 cm, 110 cm	Substantially Equivalent. The tubing length of the subject device is within the range of tubing lengths offered by the predicate.
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 or P-Cap assembly.	Same. Both devices use a Luer lock connection to infusion pump.
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.	Same
Infusion Site Skin Adhesive	Non-woven adhesive	Non-woven adhesive	Same
Anatomical Location	Abdomen, upper leg, upper buttocks, hips, upper arms and lower back.	Abdomen, upper leg, upper buttocks, hips, upper arms and lower back.	Same
Sterilization Method	EO	EO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same
Single Use	Yes (Infusion set and inserter)	Yes (Infusion set and inserter)	Same
Duration of Use	Up to 72 hours	Up to 72 hours	Same
Disposal	Disposal in sharps/biohazard containers according to local regulations.	Disposal in sharps/biohazard containers according to local regulations.	Same
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	Same

7 Performance Data

The following performance data were provided to support the substantial equivalence determination and verify that the device meets its design requirements:

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018 and FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2023). The following endpoints were evaluated to support the biological safety of the Sparta Infusion Set:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subacute System Toxicity
- Pyrogenicity
- Genotoxicity
- Chemical Characterization
- Toxicological Risk Assessment
- Drug Compatibility

Bench Performance Testing

Benchtop verification testing was performed to verify specified performance across the following areas:

- Leak Resistance
- Insertion Performance
- Needle Safety
- Occlusion Performance
- Particulate
- Cannula Strength
- Pump Compatibility

Sterilization and Shelf Life

Testing was performed in compliance with the following standards to demonstrate the Sparta Infusion Set is properly sterilized and remains sterile for its labeled shelf life:

- ISO 11135:2014+A1:2018
- ISO 11138-1:2017
- ISO 11138-2:2017
- ISO 11737-1:2021
- ISO 11737-2:2019
- ANSI/AAMI ST72:2019
- ASTM F1980-16
- ISO 10993-7:2008+A1:2019
- ISO 11607-1:2019

Human Factors

Human Factors validation testing was performed according to the FDA Guidance, Applying Human Factors and Usability Engineering to Medical Devices (2016), and in compliance with ISO 62366:2020. Testing demonstrated that use of the Sparta Infusion Set is safe and effective for its intended users, uses, and use environments.

Clinical Testing

No clinical testing is required to support the Subject Device's indications for use or a substantial equivalence determination.

8 Conclusion

The results of testing demonstrate that the Sparta Infusion Set for Insulin meets all performance specifications. The minor differences between the Sparta Infusion Set and the predicate device do not raise any new or different questions of safety or effectives. The Sparta Infusion Set is substantially equivalent to the predicate device.