510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K243841

B Applicant

DEKA Research and Development

C Proprietary and Established Names

Sparta Infusion Set for Insulin

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
FPA	Class II	21 CFR 880.5440 - Intravascular Administration Set	General Hospital

II Purpose for Submission:

New Device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- The Sparta Infusion Set is indicated for subcutaneous infusion of insulin only. The Sparta Infusion Set is not intended for intravenous infusion, or for infusion of blood or blood products.

- Change the infusion set at least every 72 hours.
- Do not expose the infusion set to alcohol, disinfectants, perfumes, deodorants, cosmetics, sunscreens, or insect repellants. These substances can cause damage to the infusion set and may lead to inaccurate therapy or delays in therapy.

IV Device Description:

The Sparta Infusion Set for Insulin is a single-use, 23-inch subcutaneous infusion set that establishes a sealed fluid path from an external portable infusion pump to the patient. It is intended for use with insulin. The Sparta Infusion Set for Insulin is terminally sterilized via ethylene oxide. The Sparta Infusion Set for Insulin consists of the following elements:

Tubing Set: The Tubing Set provides a fluid pathway between the infusion pump and the Infusion Site. It consists of a female Luer connector, a 23-inch transparent tubing, a base connector, and a 27-gauge stainless steel connector needle.

Infusion Site: The Infusion Site maintains the Cannula's position in the subcutaneous tissue and enables connection to, and temporary disconnection from, the Tubing Set. The Infusion Site is composed of the following components:

- Adhesive Patch: The Adhesive Patch secures the Infusion Site to the skin to maintain the Cannula's position during use.
- Infusion Set Base: The Infusion Set base locates the cannula relative to the adhesive. Throughout the duration of therapy, latching features on the Infusion Set Base hold the Cannula in the subcutaneous tissue. Infusion Set Base also interacts with the Base Connector of the tubing set to securely connect the Infusion Site to the Tubing Set.
- Cannula Base: Features on the Cannula Base interact with the Infusion Set Base to secure the Cannula in the subcutaneous tissue after Insertion. Cannula Base also interacts with the Inserter to release the Infusion Set Base during Insertion leaving the Infusion Site secured to the patient's skin.
- Cannula: The Cannula extends 6 mm into the subcutaneous tissue. It completes and maintains the fluid pathway into the patient.
- Septum: The septum creates a seal between the Tubing Set and the Infusion Site during therapy. It also self-seals when the Tubing Set is disconnected.
- Septum Retainer: Septum Retainer compresses the silicone Septum against the Cannula Base and the Cannula. This creates a leak tight seal in the Septum and allows it to self-seal when the Tubing Set is disconnected.

Inserter: The Inserter is a single-use mechanical device that inserts the Cannula into the subcutaneous tissue. The Infusion Site, including the cannula, comes pre-assembled within the Inserter. The user applies the adhesive patch to their skin and pulls the Inserter away from the body to activate it. The Inserter automatically retracts the introducer needle back into the device immediately following insertion, leaving the Infusion Site adhered to the skin.

V Substantial Equivalence Information:

A Predicate Device Name(s):
MiniMed Mio Advance infusion set

B Predicate 510(k) Number(s):
K173879

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243841	K173879
Device Trade Name	Sparta Infusion Set for Insulin	MiniMed Mio Advance infusion set
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin from an external pump. Single use.	Same
Anatomical Location	Abdomen, upper leg, upper buttocks, hips, upper arms and lower back.	Same
Duration of Use	Up to 72 hours	Same
Tubing set disconnection/ reconnection	Tubing set can be disconnected from and reconnected to infusion site.	Same
Inserter lock	Inserter lock prevents inserter activation until removed.	Same
General Device Characteristic Differences		
Cannula length	6 mm	6mm, 9mm
Tubing Length	23 inch (58.4 cm)	46 cm, 60 cm, 110 cm
Connection to external infusion pump	via standard Luer lock connection.	via standard Luer lock connection or P-Cap assembly.

VI Standards/Guidance Documents Referenced:

- ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ST67:2019, Sterilization of health care products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"
- ANSI AAMI ST72:2019, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing
- AAMI TIR17:2017/(R)2020, Compatibility of materials subjected to sterilization
- ASTM E3251:2020, Standard test method for microbial ingress testing on single-use systems

- ASTM F1140/F1140M-13 (Reapproved 2020)e1, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Package
- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1608-21, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
- ASTM F2096-11 (Reapproved 2019), Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 10993-3 Third edition 2014-10-1, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4 Third edition 2017-04, Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
- ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6 Third edition 2016-12-01, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- ISO 10993-7 Second edition 2008-10-15, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
- ISO 10993-9 Third edition 2019-11, Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11 Third edition 2017-09, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12 Fifth edition 2021-01, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-16 Third edition 2017-05, Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
- ISO 10993-17 First edition 2002-12-01, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18 Second edition 2020-01 Amendment 1 2022-05, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process [Including Amendment 1 (2022)].
- ISO TS 10993-19 Second edition 2020-03
  Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials
- ISO TS 10993-20 First edition 2006-08-01, Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO TR 10993-33 First Edition 2015-03-01, Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3

- ISO 11135 Second edition 2014-07-15, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ISO 11138-2:2017, Sterilization of health care products — Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 11607-1 Second edition 2019-02, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11737-1 Third edition 2018-01 [Including AMD1:2021], Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
- ISO 11737-2 Third edition 2019-12, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices
- ISO 15223-1 Fourth edition 2021-07, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- ISO TS 21726 First edition 2019-02, Biological evaluation of medical devices - Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
- ISO 23908 First edition 2011-06-11, Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 7864 Fourth edition 2016-08-01, Sterile hypodermic needles for single use - Requirements and test methods
- ISO 8536-8 Second Edition 2015-06-15, Infusion Equipment for Medical Use - Part 8: Infusion Sets for Single Use with Pressure Infusion Apparatus
- ISO 8536-9 Second Edition 2015-06-15, Infusion Equipment for Medical Use - Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment
- ISO 80369-7 Second edition 2021-05, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISTA 3A 2018, Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
- USP <788> Particulate Matter in Injections
- ISO 11138-1 Third edition 2017-03, Sterilization of health care products - Biological indicators - Part 1: General requirements
- AAMI TIR28:2016(R2024), Product adoption and process equivalence for ethylene oxide sterilization

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The following verification (bench) tests were conducted:

1. Leak resistance
2. Insertion performance
3. Needle safety

4. Occlusion
5. Particulate
6. Coring
7. Cannula strength
8. Operating conditions
9. Shipping and storage
10. Biocompatibility testing in accordance with ISO 10993-1
11. Sterilization

B Other Supportive Instrument Performance Characteristics Data:

Insulin Compatibility Testing

To demonstrate compatibility of the Sparta infusion set with the intended use insulin products, an infusion simulation study was performed to evaluate the stability of insulin products that were delivered over a 7-day period using a clinically relevant infusion rate with bolus deliveries and infusion pause durations. Insulin product quality testing was performed for samples collected after the simulated infusion according to respective monographs for the insulin products. The tested attributes include potency, impurities, pH, appearance, high molecular weight proteins, preservative content, and zinc content. Sub-visible particle testing is also performed. For all the insulin product lots, no significant impact from simulated infusion is observed for any of the product quality attributes tested, except for a decrease in phenolic preservative content.

Loss of phenolic preservative is a well-known phenomenon in insulin infusion sets. To determine if the degree of preservative loss was substantially equivalent to on market devices, additional drug compatibility testing was conducted to compare preservative content of insulin delivered through the Sparta Infusion Set with those from two other commercially marketed infusion sets intended for subcutaneous delivery of insulin. The DEKA ACE Pump System (K241178) was used to deliver insulin through the Sparta Infusion Set as well as two other legally marketed infusion sets. Ten (10) infusion sets for each infusion set were connected to infusion pumps. Samples were collected over the labeled 72-hour use life from the end of the infusion sets. The drug preservative contents were measured for the collected samples and for controls. Results demonstrate that the Sparta Infusion Set has equivalent preservative content performance to other commercially available infusion sets indicated for subcutaneous delivery of insulin.

Pump Compatibility Testing

To demonstrate compatibility with an FDA-cleared insulin infusion pump, the Sparta Infusion Set was tested with the DEKA ACE pump (K213536) to evaluate the ability of the pump to perform within its limits with regards to occlusion detection time and bolus upon occlusion release when connected to the Sparta System. Eight Sparta Infusion Set samples were tested. For each sample, three delivery rates that represent the full range of pump capability were tested using the same Infusion Set. Testing results demonstrated that the Sparta Infusion Set does not impact the DEKA ACE pump's performance and is therefore compatible.

Human Factors Validation

A Human Factors validation testing was performed with 33 subjects of the intended user groups, including 16 independent use patients (≥17 years of age) and 17 dyads with pediatric patients (≤16 years of age) and their caregivers. The subjects include an even mix of participants from each user group with and without subcutaneous infusion set experience. The results of the

simulated-use Human Factors validation study for the Sparta Infusion Set support a substantial equivalence decision.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.