510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K242692

B Applicant

Capillary Biomedical, LLC

C Proprietary and Established Names

SteadiSet Infusion Set

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
FPA	II	21 CFR 880.5440 – Intravascular administration set	General Hospital

E Purpose for Submission:

New Device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The SteadiSet Infusion Set is indicated for the subcutaneous infusion of insulin administered by an external pump. The infusion set is indicated for single use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

SteadiSet infusion set is neither intended nor indicated for use with blood, blood products, or intravenous infusion (IV).

Replace the infusion set and tubing every 2-3 days per your healthcare professional's instructions.

SteadiSet Infusion Set is a single-use device and should be disposed of immediately after use. Do not clean, re-sterilize, or re-use the set. This may cause damage to the set and may lead to infection, site irritation, or inaccurate delivery.

SteadiSet is not indicated for use in an MRI environment or during radiation therapy. Remove the infusion set prior to MRI or radiation therapy.

The SteadiSet infusion set with t:lock tubing connector should only be used with Tandem cartridges featuring the t:lock connector.

III Device Description

The device is a sterile, non-pyrogenic, intravascular administration set device used to administer insulin from a reservoir cartridge to a patient subcutaneously through a cannula. The infusion set administers insulin by means of a compatible external pump. The infusion set consists of an inserter, tube set, and disconnect cover. The inserter consists of a housing, insertion buttons, an infusion set hub (with cannula) and adhesive patch with protective liner. The inserter facilitates insertion of the cannula subcutaneously. The cannula is a soft medical-grade polymer extruded over a stainless-steel coil.

The tube set provides the insulin pathway between the hub's indwelling cannula and an external insulin pump cartridge. The tube set consists of infusion set tubing with a reservoir connector (proximal end) and hub connector (distal end).The disconnect cover can be connected to the hub to provide cover when the infusion set tubing is disconnected from the hub.

The device is sterilized by Ethylene Oxide (ETO) and is a single-patient, single-use device to be used for up to 3 days.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

AutoSoft™ 30 infusion set

B Predicate 510(k) Number(s):

K061374

C Comparison with Predicate(s):

Device & Predicate Device(s):	K061374	K242692

Device Trade Name	AutoSoft™ 30 Infusion Set	SteadiSet Infusion Set
General Device Characteristic Similarities		
Intended Use/Indications For Use	Subcutaneous infusion of insulin administered by an external pump. The infusion set is indicated for single use.	Same
Time of Use	3 days	Same
Compatible Devices	Tandem cartridges featuring the t:lock™ connector	Same
Sterilization	Ethylene Oxide (ETO)	Same
General Device Characteristic Differences		
Cannula Material	Teflon Cannula	Polyether amide TPE & Stainless-Steel coil Cannula
Tube Length	23 and 43 inches	5, 23, 32, and 43 inches
End configuration	Distal Connector Needle	Distal Hub Connector
Connect type	Distal Cannula housing click-in	Distal Rotational hub connector
Insertion Angel	30 degrees	35 ± 5-degrees
Cannula Material	Polytetraflouroethylene (Teflon)	Polyether amide TPE &

V Standards/Guidance Documents Referenced:

ISO 80369-6, First Edition 2016-03-15 - Small bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications

ISO 8536-4, Sixth edition 2019-09 Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed.

ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

ASTM F88/F88M-23, Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F1980-21,Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM D4332-22, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

ISO 10993-2 Third edition 2022-11, Biological evaluation of medical devices – Part 2: Animal welfare

ISO 10993-3 Third edition 2014-10-1, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

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 10993-10 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 Fourth Edition 2012-07-01, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-12 Fifth edition 2021-01, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-17 Second Edition 2023-09, Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents

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 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

ISO/TR 10993-33 First, Biological evaluation of medical devices – Part 33: Guidance on Partial

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.

ASTM F2503-23, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

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 20417 First edition 2021-04 Corrected version 2021-12 Medical devices – information to be supplied by the manufacturer.

VI Performance Characteristics:

A. Analytical Performance

N/A

B. Other Supportive Instrument Performance Characteristics Data

The following additional tests were conducted:

1. Functional tests
   - Mechanical Integrity:
     - Cannula Pull
     - Hub Connector and Tubing Pull
     - Tubing Elongation
     - T:lock and Tubing Pull Force
   - Performance Tests:
     - Mass Flow Rate
     - Pressure Leak.
     - Tubing and Cannula Priming

    - Insertion Force and Depth
2. Usability/Human Factors
    - Simulated-Use Human Factors Validation
3. Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity
    - Subacute Toxicity
    - Genotoxicity
    - Implantation
    - Sub-chronic Toxicity
4. Sterilization and Shipping
    - Sterility Assurance Level 10-6
    - Shipping, Shelf-Life, and Aging Transportation Tests
5. Compatibility Tests
    - Drug and Device Compatibility
6. Shelf-Life and Aging Testing
7. Packaging
    - Free-fall drop, package sterile barrier testing, and climatic stressing and shipping testing

VII Proposed Labeling:

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

VIII Conclusion:

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