May 9, 2025

Capillary Biomedical, LLC.
Karen Mudd
Director, Regulatory Affairs
2 Wrigley, Suite 100
Irvine, California 92618

Re: K242692
Trade/Device Name: SteadiSet Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 31, 2025
Received: March 31, 2025

Dear Karen Mudd:

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.

Submission Number *(if known)*

K242692

Device Name

SteadiSet Infusion Set

Indications for Use *(Describe)*

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.

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.

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"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."

510(k) Summary

Date: September 5, 2024

I. SUBMITTER

Address	Capillary Biomedical, Inc 2 Wrigley, Suite 100 Irvine, California 92618 USA +1 (858-366-6900)
Contact Person	Karen Mudd, PhD Director, Regulatory Affairs Phone: +1 (805) 403-9454

II. DEVICE

Proprietary / Trade Name	SteadiSet Infusion Set
Common Name	Infusion Set
Classification Name	Intravascular administration set
Classification Regulation	21 CFR 880.5440
Regulatory Class	Class II
Product Code	FPA

III. PREDICATE DEVICE

Predicate Device	K061374, AutoSoft™ 30 Infusion Set

IV. DEVICE BRIEF DESCRIPTION

The subject device, Capillary Biomedical, Inc. SteadiSet Infusion Set, 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.

V. INDICATIONS 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Predicate Device K061374	Subject Device
Product Code	FPA	Same
Regulation Number	21 CFR 880.5440	Same
Indication for Use/Intended Use	The AutoSoft™ 30 infusion set is indicated for the subcutaneous infusion of insulin administered by an external pump. The infusion set is indicated for single use	Same
Use Type	Single Use	Same
Time of Use	3 days	Same
Compatible Devices	Tandem cartridges featuring the t:lock™ connector	Same
Sterilization	Ethylene Oxide (ETO)	Same
Material Composition		
Metallic Components	Yes	Same
PVC Plasticizers	No	Same
Additives	Colorant Pigments	Same
Cannula Material	Teflon Cannula	Polyether amide TPE & Stainless-Steel coil Cannula
Physical Specifications		
Dimensions	ID 0.38mm	Same
	OD 1.50mm	Same
	Tube Length 23 and 43 inches	Tube Length 5, 23, 32, and 43 inches
	Cannula Length 13mm	Same
Priming Volume	≤0.2 mL	Same
End Configuration	Distal Connector Needle	Distal Hub Connector
	Proximal Reservoir Connector	Same
Connector Type	Distal Cannula housing click-in	Distal Rotational hub connector
	Proximal t:lock reservoir connector	Same
Tubing Color	No colorant Clear/transparent	Same

VII. NON-CLINICAL PERFORMANCE DATA

Performance Characteristic	Testing Performed
Bench Testing	Insertion Force and Depth
	Strength of Materials, Joints, and Connectors
	Tubing and Cannula Priming

	Tubing Elongation
	Functional Performance
	Tandem Pump Compatibility
	Corrosion Testing
Usability/Human Factors	Simulated-Use Human Factors Validation
Biocompatibility	Cytotoxicity
	Sensitization
	Irritation
	Acute Systemic Toxicity
	Material Mediated Pyrogenicity
	Subacute Toxicity
	Genotoxicity
	Implantation
	Sub-chronic Toxicity
Sterilization and Shipping	Sterility Assurance Level 10^{-6}
	Shipping, Shelf-Life, and Aging

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION SUMMARY

Guidance document, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* July 28, 2014, was consulted in determining substantial equivalence between the subject and predicate device.

The predicate device is legally marketed. The predicate device labeling has been reviewed and is consistent with IFU statements for the subject device. The devices have the same intended use. As shown in comparison table above, the design, materials, energy source and other features of the devices have been reviewed. There are differences noted between the two devices, indicating that the devices do not have the same technological characteristics as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A). The different technological characteristics of the devices do not raise new questions of safety and effectiveness.

IX. CONCLUSIONS

Per the comparison and analysis above, the subject device is determined to be substantially equivalent (SE) to the predicate device.