April 3, 2025

Fresenius Medical Care Renal Therapies Group, LLC
Caitlin Kalda
Senior Lead - RA Home
920 Winter Street
Waltham, MA 02451

Re: K250404
Trade/Device Name: stay•safe® catheter extension set with Safe- Lock, 12 inch; stay•safe® catheter extension set with Luer-Lock, 6 inch; stay•safe® catheter extension set with Luer-Lock, 12 inch; stay•safe® catheter extension set with Luer-Lock, 18 inch; stay•safe® to Luer-Lock Adapter, 4 inch
Regulation Number: 21 CFR § 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: KDJ
Dated: February 12, 2025
Received: February 12, 2025

Dear Caitlin Kalda:

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); 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,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
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)*

K250404

Device Name

stay•safe® catheter extension set with Safe- Lock, 12 inch;
stay•safe® catheter extension set with Luer-Lock, 6 inch;
stay•safe® catheter extension set with Luer-Lock, 12 inch;
stay•safe® catheter extension set with Luer-Lock, 18 inch;
stay•safe® to Luer-Lock Adapter, 4 inch

Indications for Use *(Describe)*

stay•safe® catheter extension set with Safe- Lock, 12 inch:
The stay•safe catheter extension set with Safe-Lock is indicated for use in patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe catheter extension set with Safe-Lock is used to connect a PD catheter with Safe-Lock compatible catheter adapter to PD systems that use stay•safe PIN technology.

stay•safe® catheter extension set with Luer-Lock, 6 inch;
stay•safe® catheter extension set with Luer-Lock, 12 inch;
and stay•safe® catheter extension set with Luer-Lock, 18 inch:
The stay•safe catheter extension set with Luer-Lock is indicated for use in patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe catheter extension set with Luer-Lock is used to connect a PD catheter with Luer-Lock catheter adapter to PD systems that use stay•safe PIN technology.

stay•safe® to Luer-Lock Adapter, 4 inch:
The stay•safe to Luer-Lock adapter is indicated for use in patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe to Luer-Lock adapter is used to connect a stay•safe catheter extension set to medical devices with a Luer-Lock connection.

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.

1. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR §807.92.

1.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Contact Person:	Caitlin Kalda, Senior Lead RA – Home
Phone:	(857) 291-0009
Alternate Contact:	Denise Oppermann, Vice President Regulatory Affairs – North America
Phone:	(781) 996-9103
Preparation Date:	12 February 2025

1.2. Device Name

Trade Name:	stay•safe® catheter extension set with Safe-Lock, 12 inch stay•safe® catheter extension set with Luer-Lock, 6 inch stay•safe® catheter extension set with Luer-Lock, 12 inch stay•safe® catheter extension set with Luer-Lock, 18 inch stay•safe® to Luer-Lock Adapter, 4 inch
Common Name:	Safe-Lock Extension Set Luer-Lock Extension Sets Luer-Lock Adapter
Regulation Name:	Peritoneal Dialysis System and Accessories
Regulatory Class:	Class II per 21 CFR §876.5630
Product Code:	KDJ
Product Code Name:	Set, Administration, For Peritoneal Dialysis, Disposable
FDA Review Panel:	Gastroenterology/Urology

1.3. Legally Marketed Predicate Devices

A medical device correction letter was issued for the predicate devices. No removal of the product was required.

1.3.1. Predicate Devices

The stay•safe® catheter extension set with Safe-Lock, 12 inch, stay•safe® catheter extension set with Luer-Lock, 6 inch, stay•safe® catheter extension set with Luer-Lock, 12 inch, stay•safe® catheter extension set with Luer-Lock, 18 inch, and stay•safe® to Luer-Lock adapter, 4 inch (K173593) are the legally marketed predicate devices.

1.4. Device Description

1.4.1. Device Identification

The stay•safe® catheter extension set with Safe-Lock, 12 inch (Safe-Lock extension set) stay•safe® catheter extension set with Luer-Lock, 6 inch, stay•safe® catheter extension set with Luer-Lock, 12 inch, and stay•safe® catheter extension set with Luer-Lock, 18 inch (Luer-Lock extension sets), and stay•safe® to Luer-Lock adapter, 4 inch (Luer-Lock adapter), hereinafter collectively referred to as the "Catheter Extension Sets" are the subject devices of this 510(k).

1.4.2. Device Characteristics

The Safe-Lock extension set is a single-use device designed to connect a PD catheter to PD systems that use the stay•safe PIN technology. The Safe-Lock extension set is provided sterile and non-pyrogenic. The Safe-Lock extension set is sterilized using ethylene oxide (EO).

The Luer-Lock extension sets are single-use devices designed to connect a PD catheter to PD systems that use the stay•safe PIN technology. The Luer-Lock extension sets are provided sterile and non-pyrogenic. The Luer-Lock extension sets are sterilized using EO.

The Luer-Lock adapter is a single-use device designed to connect a stay•safe catheter extension set to a medical device with a Luer lock connector. The Luer-Lock adapter is provided sterile and non-pyrogenic. The Luer-Lock adapter is sterilized using EO.

1.4.3. Environment of Use

The Catheter Extension Sets are used in both healthcare and home environments.

1.4.4. Brief Written Description of the Device

The stay•safe catheter extension set with Safe-Lock, 12 inch is a single-use, sterile (EO), non-pyrogenic disposable accessory. The Safe-Lock extension set is used to connect a PD catheter with a Safe-Lock-compatible catheter adapter to PD systems that use the stay•safe PIN technology. The Safe-Lock extension set is connected to the patient's Safe-Lock-compatible catheter adapter in a hospital or clinic setting by a healthcare professional and is routinely monitored during patient follow-up visits. The extension set is intended to be connected to the patient's Safe-Lock-compatible catheter adapter for up to six (6) months and then replaced with a new one with treatment lasting up to 10 years. The extension set is used in patients for up to 10 years.

The stay•safe catheter extension set with Luer-Lock is a single-use, sterile (EO), non-pyrogenic disposable accessory. It is available in three (3) lengths: 6 inch, 12 inch, and 18 inch. The Luer-Lock extension sets are used to connect a PD catheter with a Luer-Lock catheter adapter to PD systems that use the stay•safe PIN technology. The Luer-Lock extension sets are connected to the patient catheter adapter in a hospital or clinic setting by a healthcare professional and are routinely monitored during patient follow-up visits. The Luer-Lock extension set is intended to be connected to the patient's catheter adapter for up to 6 months and then replaced with a new

one with treatment lasting up to 10 years. The Luer-Lock extension set is used in patients for up to 10 years.

The stay•safe to Luer-Lock adapter is a single-use, sterile (EO), non-pyrogenic disposable accessory that is used to connect a stay•safe catheter extension set to a medical device with a Luer lock connection (e.g., transfer set or syringe). The Luer-Lock adapter consists of a stay•safe connector, tubing, and a Luer lock connector. The Luer-Lock adapter is connected to the stay•safe catheter extension set in a hospital or clinic setting by a healthcare professional. The Luer-Lock adapter is intended to be connected for up to 6 months and then replaced with a new one with treatment lasting up to 10 years. The Luer-Lock adapter is used in patients for up to 10 years.

1.4.5. Materials of Use

The Catheter Extensions Sets are classified as externally communicating blood path indirect, permanent contact (> 30 day) duration devices in accordance with FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (September 2023).

The materials used in the Safe-Lock extension set, Luer-Lock extension set, and Luer-Lock adapter are provided in Table 1.

Table 1: Materials Used in Catheter Extension Sets

Component	Material
Safe-Lock Extension Set	
Protective cap	Polypropylene Silicone
Male stay•safe connector	Polyvinylidene fluoride
Tubing	Silicone
Clamp	Polyoxymethylene
Male Safe-Lock connector	Polycarbonate
Blue cap	Polyether block amide
Luer-Lock Extension Set	
Protective cap	Polypropylene Silicone
Male stay•safe connector	Polyvinylidene fluoride
Tubing	Silicone
Clamp	Polyoxymethylene
Male Luer-Lock connector	Thermoplastic elastomer

Table 1: Materials Used in Catheter Extension Sets

Component	Material
Blue cap	Low-density polyethylene
Luer-Lock Adapter	
Closure Cap	Polyamide block ether
Female Luer-Lock connector	Polyvinylidene fluoride
Tubing	Silicone
Female stay•safe adapter	Polyvinylidene fluoride
stay•safe cap	Polypropylene Silicone

1.4.6. Key Performance Specifications/Characteristics

The Safe-Lock and Luer-Lock extension sets provide additional length to the patient's catheter and allow for connection to the stay•safe system for PD treatment. The Safe-Lock and Luer-Lock extension sets enable effluent to drain out of, and dialysate to flow into, the patient's peritoneum during PD treatment.

The stay•safe to Luer-Lock adapter converts the stay•safe end of the patient's catheter extension set into a Luer lock to make it compatible with medical devices that have a Luer lock connection.

1.5. Intended Use/Indications for Use

1.5.1. stay•safe catheter extension set with Safe-Lock (Safe-Lock extension set)

Intended Use

The stay•safe catheter extension set with Safe-Lock is intended for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD).

Indications for Use

The stay•safe catheter extension set with Safe-Lock is indicated for use in patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe catheter extension set with Safe-Lock is used to connect a PD catheter with Safe-Lock compatible catheter adapter to PD systems that use stay•safe PIN technology.

1.5.2. stay•safe catheter extension sets with Luer-Lock (Luer-Lock extension sets)

Intended Use

The stay•safe catheter extension set with Luer-Lock is intended for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD).

Indications for Use

The stay•safe catheter extension set with Luer-Lock is indicated for use in patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe catheter extension set with Luer-Lock is used to connect a PD catheter with a Luer-Lock catheter adapter to PD systems that use stay•safe PIN technology.

1.5.3. stay•safe to Luer-Lock adapter (Luer-Lock adapter)

Intended Use

The stay•safe to Luer-Lock adapter is intended for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD).

Indications for Use

The stay•safe to Luer-Lock adapter is indicated for use in patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe to Luer-Lock adapter is used to connect a stay•safe catheter extension set to medical devices with a Luer-Lock connection.

1.6. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Catheter Extension Sets are substantially equivalent to those of the predicate devices (K173593):

- Intended Use
- Indications for Use
- Design Specifications
- Technological Characteristics
- Principle of Operation
- Performance Requirements

1.7. Performance Data

The following performance tests were conducted on the Catheter Extension Sets to support the determination of substantial equivalence:

- Weight Verification
- Length Verification
- Clamp Occlusion
- Clamp Compression
- Visual Inspection after Challenge Condition
- Leak Test

- Bond/Tensile Strength
- Shipping and Packaging
- Tubing Verification – Dimensional

1.7.1. Biocompatibility Testing

The Catheter Extensions Sets were evaluated for biocompatibility in accordance with *ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* 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"* (September 2023).

The following endpoints were evaluated to support the biological safety of the Catheter Extension Sets:

- Chemical Characterization
- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity (acute to chronic)
- Pyrogenicity
- Genotoxicity
- Hemocompatibility
- Carcinogenicity

1.7.2. Human Factors Validation Testing

Human Factors testing was not required.

1.7.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The Catheter Extension Sets are not electrical mechanical devices.

1.7.4. Software Verification and Validation Testing

Not applicable. The Catheter Extension Sets do not contain software.

1.7.5. Animal Studies

No animal studies were performed for the Catheter Extension Sets.

1.7.6. Clinical Studies

No clinical studies were performed for the Catheter Extension Sets.

1.8. Conclusion

The indications for use, design, principle of operation, and technological characteristics of the Catheter Extension Sets are substantially equivalent to those of the predicate devices. Test results demonstrate that the differences between the Catheter Extension Sets and the predicate devices do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the stay•safe® catheter extension set with Safe-Lock, 12 inch, stay•safe® catheter extension set with Luer-Lock, 6 inch, stay•safe® catheter extension set with Luer-Lock, 12 inch, stay•safe® catheter extension set with Luer-Lock, 18 inch, and stay•safe® to Luer-Lock adapter, 4 inch are substantially equivalent to the selected predicates.