February 14, 2018

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: K173651
Trade/Device Name: Multiple Tubing Segment (MTS) Set with stay·safe® PIN Connectors, stay·safe® Drain Set
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: KDJ
Dated: November 24, 2017
Received: November 29, 2017

Dear Denise Oppermann:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173651

Device Name
Multiple Tubing Segment (MTS) Set with stay•safe® PIN Connectors
stay•safe® Drain Set

Indications for Use *(Describe)*

Multiple Tubing Segment (MTS) Set with stay•safe® PIN Connectors:
The Multiple Tubing Segment (MTS) Set with stay•safe PIN Connectors is indicated for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The MTS Set is placed during set-up to make additional connections to the cycler set when prescribed or when an interruption in treatment is necessary. This device is compatible with stay•safe Peritoneal Dialysis (PD) connectology system and is to be used only with Fresenius Medical Care (FMCNA) Cyclers and Cycler Sets.

stay•safe® Drain Set:
The stay•safe Drain Set is indicated for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe Drain Set is used to connect directly to the stay•safe catheter extension set to enable drainage and/or effluent sampling as needed. This device is compatible with Fresenius Medical Care (FMCNA) Peritoneal Dialysis (PD) stay•safe catheter extension sets.

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.

5. 510(K) SUMMARY

A 510(k) summary for each device is provided in Section 5.1 (Multiple Tubing Segment (MTS) Set with stay•safe® PIN connectors), and Section 5.2 (stay•safe® Drain Set).

5.1. Multiple Tubing Segment (MTS) Set with stay•safe® PIN Connectors

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.

5.1.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs – Devices
Preparation Date:	24 November 2017

5.1.2. Device Name

Trade Name:	Multiple Tubing Segment (MTS) Set with stay•safe® PIN Connectors
Common Name:	MTS Set
Classification Name:	Peritoneal Dialysis System and Accessories
Regulatory Class:	Class II per 21 CFR §876.5630
Product Code:	KDJ
Classification Panel:	Gastroenterology/Urology

5.1.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Fresenius stay•safe Patient Connectors (K041792). This predicate has not been subject to a design-related recall.

5.1.4. Device Description

5.1.4.1. Device Identification

The Multiple Tubing Segment (MTS) Set with stay•safe® PIN Connectors (hereinafter referred to as "MTS Set") is the subject of this 510(k).

5.1.4.2. Device Characteristics

The MTS Set is a single-use device that provides additional connections/disconnections when used with a stay•safe compatible cycler set during acute and chronic peritoneal dialysis (PD) treatment. The MTS Set is provided sterile and non-pyrogenic. The MTS Set is sterilized using ethylene oxide (EO).

5.1.4.3. Environment of Use

The MTS Set is used in both healthcare and home environments.

5.1.4.4. Brief Written Description of the Device

The MTS Set is a single-use, sterile (EO), non-pyrogenic, optional accessory that provides additional connections/disconnections when used with a stay•safe compatible cycler set during acute and chronic PD treatment. The MTS Set utilizes the same PIN engagement technology used in Fresenius stay•safe Patient Connectors (K041792). The MTS Set consists of two (2) stay•safe PIN Connectors at the proximal end, tubing, and a Safe-Lock connector at the distal end. The MTS Set is attached to a cycler set by a patient, care partner, or healthcare professional. The MTS Set is attached during setup to make additional connections to the cycler set when they are prescribed by a physician or when an interruption in treatment is necessary.

5.1.4.5. Materials of Use

The MTS Set is classified as externally communicating, blood path indirect, prolonged contact (> 24 hours to 30 days) duration, Class II (Category B) device 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"* (16 June 2016).

The MTS Set components are composed of the following materials:

Components	**Material**
PD filter assembly cap	Polypropylene Acrylic (Membrane)
Male tubing connector (frosted)	Polycarbonate
stay•safe assembly (clear body connector)	Polycarbonate Polypropylene Silicone
Tubing	Polyvinyl chloride
stay•safe assembly (clear body connector) with clear cap	Polycarbonate Polypropylene Silicone
Male Safe-Lock connector	Polycarbonate
Cap, Male connector	Ethylene vinyl acetate

5.1.4.6. Key Performance Characteristics

The MTS Set is an optional accessory that allows additional connections/disconnections by providing a sterile fluid path with secure connections (stay•safe® and Safe-Lock®), when used with a stay•safe compatible cycler set.

5.1.5. Intended Use

The Multiple Tubing Segment (MTS) Set with stay•safe PIN Connectors is intended for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD).

5.1.6. Indications for Use

The Multiple Tubing Segment (MTS) Set with stay•safe PIN Connectors is indicated for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The MTS Set is placed during set-up to make additional connections to the cycler set when prescribed or when an interruption in treatment is necessary. This device is compatible with stay•safe Peritoneal Dialysis (PD) connectology system and is to be used only with Fresenius Medical Care (FMCNA) Cyclers and Cycler Sets.

5.1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the MTS Set are equivalent to the predicate Fresenius stay•safe Patient Connectors (K041792).

- Intended use
- Principle of operation
- Sterilization method
- Design characteristics

5.1.8. Performance Data

A summary of testing conducted to support the determination of substantial equivalence is as follows:

Test	Test Method Description	Acceptance Criteria	Results/Conclusion
Tubing verification	The inner diameter (ID) and outer diameter (OD) of the MTS Set tubing was measured using a calibrated non-contact measurement system. The hardness of the resin of the MTS Set tubing was measured using a durometer.	The PVC tubing shall have an ID of 0.158” ± 0.005” and an OD of 0.236” ± 0.005”. The resin hardness of the PVC tubing shall be of 70 ± 3 durometer.	Pass, results within acceptance criteria

Test	Test Method Description	Acceptance Criteria	Results/Conclusion
stay•safe PIN connector and male Safe-Lock connector performance	A simulated PD treatment was performed using the MTS Set, Liberty Cycler, and Liberty Cycler Set to verify the compatibility of the stay•safe PIN connector and male Safe-Lock connector of the MTS Set with the stay•safe PD connectology system. The stay•safe patient connector of the MTS Set was inserted in the blue clip of the stay•safe organizer.	The patient and male Safe-Lock connectors shall be compatible with the stay•safe PD connectology system of the Liberty Cycler Set. No leaks or disconnections. The stay•safe patient connector shall fit with the stay•safe organizer.	Pass, results within acceptance criteria
Bond/tensile strength	An Instron machine was used to perform a pull-off test for each bonded engagement.	The test samples shall resist a minimum force of 10 lbs at each bonded engagement.	Pass, results within acceptance criteria
Packaging verification	The MTS Set packaging (polyethylene bag) was visually inspected to verify the presence of 4 (four) vents. The MTS Set packaging (polyethylene bag) was visually inspected to verify that each bag consisted of one MTS Set device.	The device bag (packaging bag) shall have 4 vents according to drawing P134D-A763. The devices shall be packaged individually in a polyethylene bag.	Pass, results within acceptance criteria
Weight verification	Cases (corrugated cartons) of MTS Sets were weighed using a calibrated scale to verify the quantity of devices per case.	The outer packaging shall contain 10 individually packaged units.	Pass, results within acceptance criteria
Shipping and packaging	A simulated shipping and distribution test was conducted per ASTM D4169-16 *Standard Practice for Performance Testing of Shipping Containers and Systems*, Distribution Cycle 13, Assurance Level II.	Visual Inspection No loose or missing caps, no kinks in tubing, no damage to components and/or tubing (cracks, holes, cuts). No damage to bag or case labels.	Pass, results within acceptance criteria

Test	Test Method Description	Acceptance Criteria	Results/Conclusion
Biocompatibility	The proposed MTS Set device was evaluated for biocompatibility in accordance with the requirements of ISO 10993-1:2009/(R)2013, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.	The proposed device is biologically safe for its intended use.	Pass, results within acceptance criteria

Results of the design verification tests met the design requirements for the proposed device and demonstrated that, like the predicate device, it is safe and effective for its intended use.

5.1.8.1. Biocompatibility Testing

Testing was performed to support the biological safety of the MTS Set.

- Simulated use Leachables
- Cytotoxicity, ISO Elution Method with MEM
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Systemic Toxicity, Short-term repeated exposure
- Materials-Mediated Pyrogenicity
- Hemocompatibility, ASTM Hemolysis (Indirect) – Extract

A toxicological risk assessment was also performed.

5.1.8.2. Human Factors Validation Testing

The MTS Set was validated for its safe and effective use in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The MTS Set is not an electrical mechanical device.

5.1.8.4. Software Verification and Validation Testing

Not applicable. The MTS Set does not contain software.

5.1.8.5. Mechanical and Acoustic Testing

No mechanical or acoustic tests were performed.

5.1.8.6. Animal Studies

No animal studies were performed.

5.1.8.7. Clinical Studies

No clinical studies were performed.

5.1.9. Conclusion

The intended use, principle of operation, sterilization method and design of the MTS Set is substantially equivalent to that of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the MTS Set device is safe and effective for its intended use.

5.2. stay•safe® Drain Set

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.

5.2.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs – Devices
Preparation Date:	24 November 2017

5.2.2. Device Name

Trade Name:	stay•safe® Drain Set
Common Name:	Drain Set
Classification Name:	Peritoneal Dialysis System and Accessories
Regulatory Class:	Class II per 21 CFR §876.5630
Product Code:	KDJ
Classification Panel:	Gastroenterology/Urology

5.2.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Peritoneal Dialysis Drainage Set (K895991). This predicate has not been subject to a design-related recall.

The Fresenius CAPD stay•safe® Disposable Administration Sets with stay•safe® Connector (K022412) and the Fresenius stay•safe Patient Connectors (K041792) are used as reference devices.

5.2.4. Device Description

5.2.4.1. Device Identification

The stay•safe® Drain Set (hereinafter referred to as "Drain Set") is the subject of this 510(k).

5.2.4.2. Device Characteristics

The Drain Set is a single-use device that connects directly to the patient's stay•safe catheter extension set to enable effluent drainage as needed. The Drain Set is provided sterile and non-pyrogenic. The Drain Set is sterilized using ethylene oxide (EO).

5.2.4.3. Environment of Use

The Drain Set is used in both healthcare and home environments.

5.2.4.4. Brief Written Description of the Device

The Drain Set is a single-use, sterile, non-pyrogenic accessory that connects directly to the patient's stay•safe catheter extension set. The Drain Set is attached to the patient's stay•safe catheter extension set by a patient, care partner, or healthcare professional. The Drain Set is used to enable effluent drainage as needed (e.g., when a patient is feeling full) after concluding Automated Peritoneal Dialysis (APD) or Continuous Ambulatory Peritoneal Dialysis (CAPD) treatment. The Drain Set consists of an empty three (3) L drain bag, a stay•safe PIN connector, a sample port, tubing, and a low force clamp. The sample port allows effluent sampling, as needed. Sampling is performed following effluent collection, per facility procedure.

5.2.4.5. Materials of Use

The Drain Set is classified as externally communicating, blood path indirect, prolonged contact (> 24 hours to 30 days) duration, Class II (Category B) device 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"* (16 June 2016).

The Drain Set components are composed of the following materials:

Components	**Material**
3 L drain bag	Polyvinyl chloride
Sample port	Polyisoprene
Clamp, low force, yellow	Polypropylene
Tubing	Polyvinyl chloride
stay•safe assembly (clear body connector)	Polycarbonate Polypropylene Silicone
PD filter assembly cap	Polypropylene Acrylic (Membrane)

5.2.4.6. Key Performance Characteristics

The Drain Set connects directly to the patient's stay•safe catheter extension set to enable effluent drainage as needed.

5.2.5. Intended Use

The Drain Set is intended for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD).

5.2.6. Indications for Use

The stay•safe Drain Set is indicated for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe Drain Set is used to connect directly to the stay•safe catheter extension set to enable drainage and/or effluent sampling as needed. This device is compatible with Fresenius Medical Care (FMCNA) Peritoneal Dialysis (PD) stay•safe catheter extension sets.

5.2.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Drain Set are equivalent to the predicate Peritoneal Dialysis Drainage Set (K895991).

- Intended use
- Sterilization method
- Principle of operation

5.2.8. Performance Data

A summary of testing conducted to support the determination of substantial equivalence is as follows:

Test	Test Method Description	Acceptance Criteria	Results/Conclusion
Tubing verification	The inner diameter (ID) and outer diameter (OD) of the Drain Set tubing was measured using a calibrated non-contact measurement system. The hardness of the resin of the Drain Set tubing was measured using a durometer.	The PVC tubing shall have an ID of 0.168" ± 0.005" and an OD of 0.265" ± 0.005". The resin hardness of the PVC tubing shall be of 70 ± 3 durometer.	Pass, results within acceptance criteria
stay•safe PIN connector performance	The stay•safe patient connector of the Drain Set was inserted in the blue clip of the stay•safe organizer.	The stay•safe patient connector shall fit with the stay•safe organizer.	Pass, results within acceptance criteria
Clamp performance	An Instron machine measured the force required to close the clamps.	Force required must be less than 10 lbf.	Pass, results within acceptance criteria

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Test	Test Method Description	Acceptance Criteria	Results/Conclusion
Drop test	The principles of ISO 15747:2010 *Plastic Containers for Intravenous Injections* were applied: The Drain Set was filled to capacity with water and dropped from a height of 0.375 m.	Acceptance criteria from ISO 15747:2010 were applied: The Drain Bag shall not leak (visual inspection).	Pass, results within acceptance criteria
Bond/tensile strength	An Instron machine was used to perform a pull-off test for each bonded engagement.	The test samples shall resist a minimum force of 10 lbs at each bonded engagement.	Pass, results within acceptance criteria
Packaging verification	A visual inspection was performed to verify that Drain Set bag has a clear and a textured side. The Drain Set packaging (polyethylene bag) were visually inspected to verify the presence of 4 vents. The Drain Set packaging (polyethylene bag) was visually inspected to verify that each bag consisted of one MTS Set device.	The Drain Set shall have a clear and a textured side. The device bag (packaging bag) shall have 4 vents according to drawing P134D-A763. The devices shall be packaged individually in a polyethylene bag.	Pass, results within acceptance criteria
Weight verification	Cases (corrugated cartons) of Drain Sets were weighed using a calibrated scale to verify the quantity of devices per case.	The outer packaging shall contain 10 individually packaged units.	Pass, results within acceptance criteria
Shipping and packaging	A simulated shipping and distribution test was conducted per ASTM D4169-16 *Standard Practice for Performance Testing of Shipping Containers and Systems*, Distribution Cycle 13, Assurance Level II.	Visual Inspection No loose or missing caps, no kinks in tubing, no damage to components and/or tubing (cracks, holes, cuts). No damage to bag or case labels.	Pass, results within acceptance criteria

Test	Test Method Description	Acceptance Criteria	Results/Conclusion
Biocompatibility	The proposed Drain Set device was evaluated for biocompatibility in accordance with the requirements of ISO 10993-1:2009/(R)2013, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.	The proposed device is biologically safe for its intended use.	Pass, results within acceptance criteria

Results of the design verification tests met the design requirements for the proposed device and demonstrated that, like the predicate device, it is safe and effective for its intended use.

5.2.8.1. Biocompatibility Testing

Testing was performed to support the biological safety of the Drain Set.

- Simulated use Leachables
- Cytotoxicity, ISO Elution Method with MEM
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Systemic Toxicity, Short-term repeated exposure
- Materials-Mediated Pyrogenicity
- Hemocompatibility, ASTM Hemolysis (Indirect) – Extract

A toxicological risk assessment was also performed.

5.2.8.2. Human Factor Validation Testing

The Drain Set was validated for its safe and effective use in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.2.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The Drain Set is not an electrical mechanical device.

5.2.8.4. Software Verification and Validation Testing

Not applicable. The Drain Set does not contain software.

5.2.8.5. Mechanical and Acoustic Testing

No mechanical or acoustic tests were performed.

5.2.8.6. Animal Studies

No animal studies were performed.

5.2.8.7. Clinical Studies

No clinical studies were performed.

5.2.9. Conclusion

The intended use, sterilization method, and principle of operation of the Drain Set is substantially equivalent to that of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the Drain Set device is safe and effective for its intended use.