May 21, 2018

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

Re: K173593
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: April 23, 2018
Received: April 24, 2018

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,

Joyce M. Whang -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)*

K173593

Device Name

stay•safe® catheter extension set with Safe-Lock, 12 inch

Indications for Use *(Describe)*

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.

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.

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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)*

K173593

Device Name

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

Indications for Use *(Describe)*

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.

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)

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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)*
K173593

Device Name
stay•safe® to Luer-Lock adapter, 4 inch

Indications for Use *(Describe)*
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.

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5. 510(k) SUMMARY

A 510(k) summary for the each device is provided in Section 5.1 (stay•safe® catheter extension set with Safe-Lock), Section 5.2 (stay•safe® catheter extension sets with Luer-Lock), and Section 5.3 (stay•safe® to Luer-Lock adapter).

5.1. 510(k) Summary for stay•safe® catheter extension set with Safe-Lock

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:	20 November 2017

5.1.2. Device Name

Trade Name:	stay•safe® catheter extension set with Safe-Lock, 12 inch
Common Name:	Safe-Lock extension 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 Dextrolyte II Peritoneal Dialysis Catheter Extension Set with Roller Clamp (K920697). 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.

5.1.4. Device Description

5.1.4.1. Device Identification

The stay•safe® catheter extension set with Safe-Lock (hereinafter referred to as "Safe-Lock extension set") is the subject of this 510(k).

5.1.4.2. Device Characteristics

The Safe-Lock extension set is a single-use device designed to connect a PD catheter to PD systems that use 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).

5.1.4.3. Environment of Use

The Safe-Lock extension set is used in both healthcare and home environments.

5.1.4.4. Brief Written Description of the Device

The Safe-Lock extension set is a single-use, sterile (EO), non-pyrogenic disposable accessory. The Safe-Lock extension set is used to connect a PD catheter that has a Safe-Lock-compatible catheter adapter to PD systems that use 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.

5.1.4.5. Materials of Use

The Safe-Lock extension set is classified as an externally communicating, blood path indirect, permanent contact (> 30 days) duration, Class II (Category C) 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 Safe-Lock extension sets are composed of the following materials:

Component	**Material**
Protective cap	Polypropylene Silicone
Male stay•safe connector	Polyvinylidene fluoride
Tubing	Silicone
Clamp	Polyoxomethylene
Male Safe-Lock connector	Polycarbonate
Blue cap	Polyether block amide

5.1.4.6. Key Performance Characteristics

The Safe-Lock extension set provides additional length to the patient's catheter and allows for connection to the stay•safe system for PD treatment. The Safe-Lock extension set enables effluent to drain out of, and dialysate to flow into, the patient's peritoneum during PD treatment.

5.1.5. 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.

5.1.6. 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.

5.1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Safe-Lock extension set are equivalent to the predicate Dextrolyte II Peritoneal Dialysis Catheter Extension Set with Roller Clamp (K920697).

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

5.1.8. Performance Data

Testing was conducted to support the determination of substantial equivalence.

- Performance
    - Tubing verification
    - Clamp performance
    - Connectology (stay•safe, Safe-Lock)
    - Package verification
    - Engagements bond/tensile strength
    - Device weight verification
    - Cleaning agents compatibility
    - Latex content verification
    - Particulate visual inspection

- Shipping and packaging

- Maintenance of sterility
- Biological safety (biocompatibility)
- Usability

5.1.8.1. Biocompatibility Testing

Testing was conducted to support the biological safety of the Safe-Lock extension set.

- Simulated Use Leachables Testing
- Cytotoxicity, ISO Elution Method with MEM
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Systemic Toxicity, Short-Term Repeated Exposure
- Material-Mediated Pyrogenicity
- Genotoxicity, Bacterial Review Mutation Assay
- Genotoxicity, *in vitro* Mouse Lymphoma Gene Mutation Assay
- Genotoxicity, Mouse Micronucleus *in vivo* Assay
- Hemocompatibility, ASTM Hemolysis (Indirect) – Extract

A toxicological risk assessment was also performed.

5.1.8.2. Human Factors Validation Testing

The Safe-Lock extension 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

Not applicable. The Safe-Lock extension set is not an electrical mechanical device.

5.1.8.4. Software Verification and Validation Testing

Not applicable. The Safe-Lock extension 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, design characteristics, and sterilization method of the Safe-Lock extension 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 Safe-Lock extension set is safe and effective for its intended use.

5.2. 510(k) Summary for stay•safe® catheter extension sets with Luer-Lock

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:	20 November 2017

5.2.2. Device Name

Trade Name:	stay•safe® catheter extension sets with Luer-Lock, 6 inch stay•safe® catheter extension sets with Luer-Lock, 12 inch stay•safe® catheter extension sets with Luer-Lock, 18 inch
Common Name:	Luer-Lock extension sets
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 Dextrolyte II Peritoneal Dialysis Catheter Extension Set with Roller Clamp (K920697). 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® catheter extension sets with Luer-Lock (hereinafter referred to as "Luer-Lock extension sets") are the subject of this 510(k).

5.2.4.2. Device Characteristics

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

5.2.4.3. Environment of Use

The Luer-Lock extension set is used in both healthcare and home environments.

5.2.4.4. Brief Written Description of the Device

The Luer-Lock extension set is a single-use, sterile (EO), non-pyrogenic disposable accessory. It is available in three (3) lengths: 6 inch (050-95013), 12 inch (050-95004), and 18 inch (050-95005). The Luer-Lock extension sets are used to connect a PD catheter that has a Luer-Lock catheter adapter to PD systems that use 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.

5.2.4.5. Materials of Use

The Luer-Lock extension sets are classified as externally communicating, blood path indirect, permanent contact (> 30 days) duration, Class II (Category C) 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"* (16 June 2016).

The Luer-Lock extension sets are composed of the following materials:

Component	**Material**
Protective cap	Polypropylene Silicone
Male stay•safe connector	Polyvinylidene fluoride
Tubing	Silicone
Clamp	Polyoxomethylene
Male LuerLock connector	Thermoplastic elastomer
Blue cap	Low-density polyethylene

5.2.4.6. Key Performance Characteristics

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

5.2.5. 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.

5.2.6. 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.

5.2.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Luer-Lock extension sets are equivalent to the predicate Dextrolyte II Peritoneal Dialysis Catheter Extension Set with Roller Clamp (K920697).

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

5.2.8. Performance Data

Testing was conducted to support the determination of substantial equivalence.

- Performance
    - Tubing verification
    - Clamp performance
    - Connectology (stay•safe, Luer-Lock)
    - Package verification
    - Engagements bond/tensile strength
    - Device weight verification
    - ISO 594-2
    - Cleaning agents compatibility
    - Latex content verification
    - Particulate visual inspection
    - Shipping and packaging
- Maintenance of sterility
- Biological safety (biocompatibility)

- Usability

5.2.8.1. Biocompatibility Testing

Testing was conducted to support the biological safety of the Luer-Lock extension set.

- Simulated Use Leachables Testing
- Cytotoxicity, ISO Elution Method with MEM
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Systemic Toxicity, Short-Term Repeated Exposure
- Material-Mediated Pyrogenicity
- Genotoxicity, Bacterial Review Mutation Assay
- Genotoxicity, *in vitro* Mouse Lymphoma Gene Mutation Assay
- Genotoxicity, Mouse Micronucleus *in vivo* Assay
- Hemocompatibility, ASTM Hemolysis (Indirect) – Extract

A toxicological risk assessment was also performed.

5.2.8.2. Human Factors Validation Testing

The Luer-Lock extension sets were validated for their 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

Not applicable. The Luer-Lock extension sets are not electrical mechanical devices.

5.2.8.4. Software Verification and Validation Testing

Not applicable. The Luer-Lock extension sets do 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, principle of operation, design characteristics, and sterilization method of the Luer-Lock extension sets are substantially equivalent to those of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the Luer-Lock extension sets are safe and effective for their intended use.

5.3. 510(K) Summary for stay•safe® to Luer-Lock adapter

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.

5.3.1. 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:	20 November 2017

5.3.2. Device Name

Trade Name:	stay•safe® to Luer-Lock Adapter, 4 inch
Common Name:	Luer-Lock adapter
Classification Name:	Peritoneal Dialysis System and Accessories
Regulatory Class:	Class II per 21 CFR §876.5630
Product Code:	KDJ
Classification Panel:	Gastroenterology/Urology

5.3.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Universal Connector (K896764). 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.

5.3.4. Device Description

5.3.4.1. Device Identification

The stay•safe® to Luer-Lock adapter (hereinafter referred to as "Luer-Lock adapter") is the subject of this 510(k).

5.3.4.2. Device Characteristics

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.

5.3.4.3. Environment of Use

The Luer-Lock adapter is used in both healthcare and home environments.

5.3.4.4. Brief Written Description of the Device

The 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.

5.3.4.5. Materials of Use

The Luer-Lock adapter is classified as an externally communicating, blood path indirect, permanent contact (> 30 days) duration, Class II (Category C) 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 Luer-Lock adapter is composed of the following materials:

Component	**Material**
Closure Cap	Polyamide block ether
Female Luer lock connector	Polyvinylidene fluoride
Tubing	Silicone
Female stay•safe adapter	Polyvinylidene fluoride
stay•safe cap	Polypropylene Silicone

5.3.4.6. Key Performance Characteristics

The 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.

5.3.5. 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.

5.3.6. 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.

5.3.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Luer-Lock adapter are equivalent to the predicate Universal Connector (K896764).

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

5.3.8. Performance Data

Testing was conducted to support the determination of substantial equivalence.

- Performance
    - Tubing verification
    - Connectology (stay•safe, Luer-Lock)
    - Package verification
    - Engagements bond/tensile strength
    - Device weight verification
    - ISO 594-2
    - Cleaning agents compatibility
    - Latex content verification
    - Shipping and packaging
- Maintenance of sterility
- Biological safety (biocompatibility)
- Usability

5.3.8.1. Biocompatibility Testing

Testing was conducted to support the biological safety of the Luer-Lock adapter.

- Simulated-use Leachables Testing

- Cytotoxicity, ISO Elution Method with MEM
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Systemic Toxicity, Short-Term Repeated Exposure
- Material-Mediated Pyrogenicity
- Genotoxicity, Bacterial Review Mutation Assay
- Genotoxicity, *in vitro* Mouse Lymphoma Gene Mutation Assay
- Genotoxicity, Mouse Micronucleus *in vivo* Assay
- Hemocompatibility, ASTM Hemolysis (Indirect) - Extract

5.3.8.2. Human Factors Validation Testing

The Luer-Lock adapter 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).

5.3.8.3. Electrical Safety and Electromagnetic Compatibility

Not applicable. The Luer-Lock adapter is not an electrical mechanical device.

5.3.8.4. Software Verification and Validation Testing

Not applicable. The Luer-Lock adapter does not contain software.

5.3.8.5. Mechanical and Acoustic Testing

No mechanical or acoustic tests were performed.

5.3.8.6. Animal Studies

No animal studies were performed.

5.3.8.7. Clinical Studies

No clinical studies were performed.

5.3.9. Conclusion

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