September 20, 2024

Sol-Millennium Medical Inc.
% Alice Huang, RA manager
Shanghai Mind-link Consulting Co., Ltd.
377 Tianzhu Road, Jiading
Shanghai, 201821, China

Re: K241821
Trade/Device Name: Luer Lock Syringe with Safety Needle; Luer Lock Syringe with Exchangeable Needle; Luer Lock Syringe with Blunt Fill Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG, FMI
Dated: June 18, 2024
Received: September 4, 2024

Dear Alice Huang:

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
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.

510(k) Number *(if known)*
K241821

Device Name
Luer Lock Syringe with Safety Needle
Luer Lock Syringe with Exchangeable Needle
Luer Lock Syringe with Blunt Fill Needle

Indications for Use *(Describe)*
The Luer Lock Syringe with Exchangeable Needle is used to inject medicines and vaccines into, or withdraw fluids from, the body.
The Luer Lock Syringe with Safety Needle is used to inject fluids into, or withdraw fluids from, the body. The safety mechanism covers the needle after use. In the activated position, the protective arm guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.
The Luer Lock Syringe with Blunt Fill Needle is used for aspiration from multi-dose medicine vials.

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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K241821 510(K) Summary

1. **Preparation date: September 20, 2024**
2. **Submitter**

Address: 311 S Wacker Drive, Suite 4100, Chicago, Illinois, 60606, United States
Contact person: Manu Kalia, Global QARA Director, +1 847-313-9577, mkalia@solm.com
Submission correspondent: Alice Huang, RA Manager, +86-15618536177, alice.huang@mind-link.net

3. **Device**

Common name:

Luer Lock Syringe with Safety Needle

Luer Lock Syringe with Exchangeable Needle

Luer Lock Syringe with Blunt Fill Needle

Trade name:

Sol-Care Luer Lock Syringe with Safety Needle

Sol-M Luer Lock Syringe with Exchangeable Needle

Sol-M Luer Lock Syringe with Blunt Fill Needle

Regulatory Information:

Classification Name: Syringe, Piston

Classification: II

Product Code: FMF

Regulation Number: 21CFR 880.5860

Review Panel: General Hospital;

Classification Name: Syringe, Antistick

Classification: II

Product Code: MEG

Regulation Number: 21CFR 880.5860

Review Panel: General Hospital;

Classification Name: Needle, Hypodermic, Single Lumen

Classification: II

Product Code: FMI

Regulation Number: 21CFR 880.5570

Review Panel: General Hospital

4. Predicate device

K221247 Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Safety Needle, Sterile Disposable Needle

5. Device description

The Luer Lock Syringe with Exchangeable Needle is a sterile, single-use, standard 3-piece piston syringe with a detachable pre-attached needle.
The Luer Lock with Safety Needle is a syringe and needle combination with the safety needle. It contains a mechanism that covers the needle point after use. In the activated position, the needle cover guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination. The Safety needle can be pre-attached or aside the syringe.
The Luer Lock Syringe with Blunt Fill Needle is a sterile, single-use, standard 3-piece piston syringe with a detachable pre-attached needle. It is used for aspiration from multi-dose medicine vials.
The proposed devices are offered in various gauge sizes and length.
The proposed devices are available in EO sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

The device is for medical professionals use only and for prescription use only.

- Luer Lock Syringe with Safety Needle (Syringe range: 1ml, 3ml, 5ml,10ml; Needle range: 20G, 21G, 22G, 23G, 25G; Needle length from 5/8” to 1 1/2"). The Safety needle can be pre-attached or aside the syringe.
- Luer Lock Syringe with Exchangeable Needle (Syringe range: 3ml, 5ml, 10ml, Needle range: 20G, 21G, 22G, 23G, 25G; Needle length from 5/8” to 1 1/2").
- Luer Lock Syringe with Blunt Fill Needle (Syringe range: 3ml, 5ml, 10ml, Needle:18G,

Needle length:1 1/2").

6. Indications for use/Intended use

The Luer Lock Syringe with Exchangeable Needle is used to inject medicines and vaccines into, or withdraw fluids from, the body.

The Luer Lock Syringe with Safety Needle is used to inject fluids into, or withdraw fluids from, the body. The safety mechanism covers the needle after use. In the activated position, the protective arm guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

The Luer Lock Syringe with Blunt Fill Needle is used for aspiration from multi-dose medicine vials.

7. Summary of Technology Characteristics

Table 1. Substantial equivalent comparison of Standard Luer Lock Syringe with Safety Needle

Item	**Proposed Device** **Luer Lock Syringe with Safety Needle**	**Predicate Device** **Sterile Disposable Syringe with Safety Needle**	**Remark**
K number	K241821	K221247	
Classification	Class II	Class II	Same
Product Code	FMF FMI MEG	FMF FMI MEG	Same
Regulation Number	21 CRF 880.5860 21 CRF 880.5570	21 CRF 880.5860 21 CRF 880.5570	Same
Indications for use	The Luer Lock Syringe with Safety Needle is used to inject fluids into, or withdraw fluids from, the body. The safety mechanism covers the needle after use. In the activated position, the protective arm guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.	The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.	Different Note 1

Configuration		Barrel, plunger, Gasket, needle cap, needle tube, needle hub with safety arm	Barrel, plunger, piston, needle hub, needle tube, needle cap, safety mechanism	Different Note 2
Operation Mode		For manual use only	For manual use only	Same
Sterilized		Yes	Yes	Same
Single use		Single use	Single use	Same
Label/Labeling		Complied with 21CFR part 801	Complied with 21 CFR part 801	Same
Syringe	Volume	1ml, 3ml, 5ml, 10ml	0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	Different Note 3
	Connect	1ml: Luer lock, Fixed; Others: Luer lock	0.5ml,1ml: Luer Lock, Luer Slip, Fixed needle; Others: Luer Lock and Luer Slip	
Needle	Size	20G, 21G, 22G, 23G, 25G	18G, 20G, 21G, 22G, 25G, 27G	
	Length	1", 5/8", 11/2"	1/2", 5/8", 3/4", 1", 1-1/4", 11/2"	
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	Same
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Luer Connector Performance		Complied with ISO 80369-7	Complied with ISO 80369-7	Same
Barrel		Polypropylene(PP)	Polypropylene(PP)	Same
Plunger		Polypropylene(PP)	Polypropylene(PP)	Same
Gasket/Piston		IR rubber	Polyisoprene	Different note 4
Needle hub		Polypropylene(PP)	Polypropylene(PP)	Same
Needle tube		Stainless Steel SUS 304	Stainless Steel SUS 304	Same
Lubricants		Silicone oil	Silicone oil	Same
Adhesive		Epoxy glue	UV adhesive	Different note 4
Cytotoxicity		No cytotoxicity	No cytotoxicity	Same
Irritation		No intracutaneous reactivity	No intracutaneous reactivity	Same
Sensitization		No sensitization	No sensitization	Same
Systemic Toxicity		No systemic toxicity	No systemic toxicity	Same
Hemolysis		No Hemolysis	No Hemolysis	Same
Pyrogen		No Pyrogen	No Pyrogen	Same

Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Discussion in details:

Note 1: Intended Use and Indications for use

Standard Luer Lock Syringe with Safety Needle and Sterile Disposable Syringe with Safety Needle have similar intended use, but are described differently. Both are intended for use in the withdrawal and injection of fluids, and the protective arm can be manually activated to cover the needle after use to minimize risk of accidental needle sticks. These differences do not raise new or different questions of safety and effectiveness when compared to the predicate device.

Note 2: Configuration

The component names of the proposed device is different to that of the predicate device; however, the components share the same configuration and function. Therefore, this difference in name will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 3: Syringe volume, Needle gauge and Needle length

The syringe volume, needle gauge and needle length of the proposed device is less than that of predicate devices. This difference in syringe and needle size will not affect the performance of the syringe and needle. In addition, the syringe and needle size of the proposed device has been tested. The test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 4: Patient-contacting Material

Although the material of the proposed and the predicate device is different, biocompatibility of the proposed device complies to the ISO 10993 series of standards. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Table 2. Substantial equivalence comparison of Luer Lock Syringe with Exchangeable Needle

Item	**Proposed Device Luer Lock Syringe with**	**Predicate Device Sterile Disposable Syringe**	**Remark**

		Exchangeable Needle	**with Needle**	
K number		K241821	K221247	
Classification		Class II	Class II	Same
Product Code		FMF FMI	FMF FMI	Same
Regulation Number		21 CRF 880.5860 21 CRF 880.5570	21 CRF 880.5860 21 CRF 880.5570	Same
Indications for use		The Luer Lock Syringe with Exchangeable Needle is used to inject medicines and vaccines into, or withdraw fluids from, the body.	The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.	Different Note 1
Configuration		Barrel, plunger, Gasket, needle cap, needle tube, needle hub	Barrel (Luer lock/Luer slip/fixed needle), plunger, piston, needle hub, needle tube, needle cap	Different Note 2
Operation Mode		For manual use only	For manual use only	Same
Sterilized		Yes	Yes	Same
Single use		Single use	Single use	Same
Label/Labeling		Complied with 21CFR part 801	Complied with 21 CFR part 801	Same
Syringe	Volume	1ml, 3ml, 5ml, 10ml	0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	Different Note 3
Needle	size	20G, 21G, 22G, 23G, 25G	18G, 20G, 21G, 22G, 25G, 27G	Different Note 3
	Length	1", 5/8", 11/2"	1/2", 5/8", 3/4", 1", 1-1/4", 11/2"	
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	Same
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Luer Connector Performance		Complied with ISO 80369-7	Complied with ISO 80369-7	Same
Barrel		Polypropylene(PP)	Polypropylene(PP)	Same
Plunger		Polypropylene(PP)	Polypropylene(PP)	Same
Gasket/Piston		IR rubber	Polyisoprene	Different Note 4
Needle hub		Polypropylene(PP)	Polypropylene(PP)	Same
Needle tube		Stainless Steel SUS 304	Stainless Steel SUS 304	Same
Needle cap		Polypropylene(PP)	Polypropylene(PP)	Same

Lubricants	Silicone oil	Silicone oil	Same
Adhesive	Epoxy glue	UV adhesive	Different Note 4
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	Same
Sensitization	No sensitization	No sensitization	Same
Systemic Toxicity	No systemic toxicity	No systemic toxicity	Same
Hemolysis	No Hemolysis	No Hemolysis	Same
Pyrogen	No Pyrogen	No Pyrogen	Same
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Discussion in details:

Note 1: Intended Use and Indications for use

The Standard Luer Lock Syringe with Exchangeable Needle and Sterile Disposable Syringe with Needle have similar intended uses, which are intended for use in the aspiration and injection of fluids. This difference does not raise new or different questions of safety and effectiveness when compared to the predicate device.

Note 2: Configuration

The component names of proposed devices are different to that of the predicate device; however, the components share the same configuration and function. Therefore, this difference in name will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 3: Syringe volume, Needle gauge and Needle length

The syringe volume, needle gauge and needle length of the proposed device is less than that of predicate devices. This difference in syringe and needle size will not affect the performance of the syringe and needle. In addition, the syringe and needle size of the proposed device has been tested. The test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 4: Patient-contacting Material

Although the material of the proposed and the predicate device is different, the patient-contacting material of the proposed device conforms to the ISO 10993 series of standards. Therefore, this difference will not affect the Substantial Equivalence (SE)

between the proposed and predicate device.

Table 3. Substantial equivalent comparison of Luer Lock Syringe with Blunt Fill Needle

Item		**Proposed Device** **Luer Lock Syringe with Blunt Fill Needle**	**Predicate Device** **Sterile Disposable Syringe with Needle**	**Remark**
K number		K241821	K221247	
Classification		Class II	Class II	Same
Product Code		FMF FMI	FMF FMI	Same
Regulation Number		21 CRF 880.5860 21 CRF 880.5570	21 CRF 880.5860 21 CRF 880.5570	Same
Indications for use		The Luer Lock Syringe with Blunt Fill Needle is used for aspiration from multi-dose medicine vials.	The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.	Different Note 1
Configuration		Barrel, plunger, Gasket, needle cap, needle tube, needle hub	Barrel (Luer lock/Luer slip/fixed needle), plunger, piston, needle hub, needle tube, needle cap	Different Note 2
Operation Mode		For manual use only	For manual use only	Same
Sterilized		Yes	Yes	Same
Single use		Single use	Single use	Same
Label/Labeling		Complied with 21CFR part 801	Complied with 21 CFR part 801	Same
Syringe	Volume	3ml, 5ml, 10ml	0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	Different Note 3
Needle	size	18G	18G, 20G, 21G, 22G, 25G, 27G	Different Note 3
	Length	11/2"	1/2", 5/8", 3/4", 1", 1-1/4", 11/2"	
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	Same
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Luer Connector Performance		Complied with ISO 80369-7	Complied with ISO 80369-7	Same

Barrel	Polypropylene(PP)	Polypropylene(PP)	Same
Plunger	Polypropylene(PP)	Polypropylene(PP)	Same
Gasket/Piston	IR rubber	Polyisoprene	Different Note 4
Needle hub	Polypropylene(PP)	Polypropylene(PP)	Same
Needle tube	Stainless Steel SUS 304	Stainless Steel SUS 304	Same
Needle cap	Polypropylene(PP)	Polypropylene(PP)	Same
Lubricants	Silicone oil	Silicone oil	Same
Adhesive	Epoxy glue	UV adhesive	Different Note 4
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	Same
Sensitization	No sensitization	No sensitization	Same
Systemic Toxicity	No systemic toxicity	No systemic toxicity	Same
Hemolysis	No Hemolysis	No Hemolysis	Same
Pyrogen	No Pyrogen	No Pyrogen	Same
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Discussion in details:

Note 1: Intended Use and Indications for use

The Indications for use of subject device and predicate device are different, but the intended use of the subject device is within the range of the predicate device. There are no new intended uses. This difference does not raise new or different questions of safety and effectiveness when compared to the predicate device.

Note 2: Configuration

The component names of the proposed devices are different to that of the predicate device; however, the components share the same configuration and function. Therefore, this difference in name will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 3: Syringe volume, Needle gauge and Needle length

The syringe volume, needle gauge and needle length of the proposed device is less than that of predicate devices. This difference in syringe and needle size will not affect the performance of the syringe and needle. In addition, the syringe and needle size of the proposed device has been tested. The test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 4: Patient-contacting Material

Although the material of the proposed and the predicate device is different, the patient-contacting material of the proposed device conforms to the ISO 10993 series of standards. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

8. Performance Data

Non-Clinical Performance Data

To verify that the proposed devices are as safe and effective as the predicate device, representative samples of the proposed device underwent a series of tests including bench testing (syringe and needle performance testing), and biocompatibility testing (cytotoxicity, sensitization, irritation, systemic toxicity, pyrogen, and hemolysis).

The test results demonstrated that the proposed device complies with the following standards:

- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
- ISO 7864:2016, Sterile hypodermic needles for single use.
- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices.
- ISO 10993-5: 2009(R), Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals.
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier

Materials.

- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- USP <85> Bacterial Endotoxins Test
- USP<151> Pyrogen Test
- USP <788> Particulate Matter Test
- ISTA 3A Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.

9. Clinical Performance Data

No data from human clinical studies have been included to support the substantial equivalence of the proposed device.

10. Conclusion

The differences between the predicate and the proposed devices do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device.