



Sang-A Frontec Co., Ltd
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine, California 92620

Re: K173743
Trade/Device Name: Greenmedi Safety Filter Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG
Dated: December 20, 2018
Received: December 26, 2018

Dear Priscilla Chung:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 4, Subpart A) for combination products; 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 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,


Sarah B. Mollo -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173743

Device Name

Greenmedi Safety Filter Syringe

Indications for Use (Describe)

The Greenmedi safety filter syringe is intended to inject the drug solutions into the human body. It is designed to prevent needle stick injuries. The 0.5um filter operates when injecting the drug into the human body to remove foreign substances from the drug solutions.

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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510(k) SUMMARY

(K173743)

Date of preparation: January 24, 2019

1. Submitted by:

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2. US Agent Contact:

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3. Device Name:

Trade Name:	Greenmedi Safety Filter Syringe
Classification:	Class II
Classification Name:	Syringe, Antistick
Product Code:	MEG
Regulation Number:	21 CFR 880.5860
Review Panel:	General Hospital

4. Predicate Device:

510k #:	K092430
Manufacturer:	Inviro Medical, Inc.
Device Name:	InviroSnap Safety Syringe

5. Device Description:

The Greenmedi safety filter syringe consists of a plunger that fits tightly within a barrel and a needle. The plunger can be linearly pulled and pushed along the inside of the tube, allowing the syringe to take in and expel liquid through a needle. After use, the health care professional fully depresses the plunger to engage the Luer Assembly. Once the Luer Assembly is engaged, pulling back the plunger causes the Adapter and the attached needle to be withdrawn into the safety of the barrel. In this position against the flange, lateral pressure on the plunger results in a controlled fracture of the plunger. Both the syringe and plunger are discarded in a sharps container.

6. Indications for Use:

The Greenmedi safety filter syringe is intended to inject the drug solutions into the human body. It is designed to prevent needle stick injuries. The 0.5um filter operates when injecting the drug into the human body to remove foreign substances from the drug solutions.

7. Technological Characteristics:

Substantial Equivalence Discussion

The Greenmedi safety filter syringe is substantially equivalent to the predicate device, InviroSnap Safety Syringe (K092430) manufactured by Inviro Medical, Inc. in terms of the device design, indications for use, and device materials.

Device Name	Subject Device	Primary Predicate Device	Comparison column	
Manufacturer	SANG-A FRONTEC CO., LTD.	Inviro Medical, Inc.	-	
Device Name	Greenmedi safety filter syringe	InviroSnap Safety Syringe	-	
510(k) Number	N/A	K092430	-	
Product Code	MEG	MEG	Same	
Indications for Use	The Greenmedi safety filter syringe is intended to inject the drug solutions into the human body. It is designed to prevent needle stick injuries. The 0.5um filter operates when injecting the drug into the human body to remove foreign substances from the drug solutions.	The InviroSnap Safety Syringe is used to inject fluids into or withdraw fluids from, the body. In addition, the InviroSnap Safety Syringe is designed to aid in the prevention of needle stick injuries.	Similar	
Design	Syringe type	Piston syringe	Piston syringe	Same
	Tip type	Luer lock	Luer lock	Same
	Syringe volume	2ml, 3ml, 5ml, 10ml	1ml, 3ml, 5ml, 10ml, 20ml	Similar
	Needle gauge	23G	21G, 22G, 23G, 25G, 27G	Same
	Needle length	17mm	12.7mm, 15.8mm, 25.4mm, 38.1mm	Similar
Materials	Needle	STS304	STS304	Same
	Lubricant For needle	Silicone Oil	Silicone Oil	Same
	Hub	Polypropylene	Polypropylene	Same
	Protective cap	Polypropylene	Polypropylene	Same
	Barrel	Polypropylene	Polypropylene	Same
	Lubricant For barrel	Silicone Oil	Silicone Oil	Same
	Plunger	Polypropylene (green)	Polypropylene	Different
	Gasket	Thermoplastic elastomer	Thermoplastic elastomer	Same

	Filter	Membrane	-	Different
	Check valve	Silicon		Different
	Principle of operation	Normal	Normal	Same
	Safety Features	The retractable type piston syringe (anti-needlestick feature)	The retractable type piston syringe (anti-needlestick feature)	Same
	Filter spec.	5µm	-	Different
	Biocompatibility	Conform ISO10993-1	Conform ISO10993-1	Same
	Particulate Testing	Conforms to USP <788>		
	Sterilization method and SAL	Sterilized by ethylene oxide gas SAL = 10 ⁻⁶	Sterilized by ethylene oxide gas SAL = 10 ⁻⁶	Same

The differences between the subject device and the predicate are the following features: check valve, filter membrane and color of the plunger. The check valve allows the fluid to pass through the needle when withdrawing from the drug solutions. During injection, the check valve is blocked, and the drug solutions passes through the filter allowing removal of particles. The subject device conforms to relevant international standards stated in Section 7. In addition, performance testing was done on the filter to ensure that the filter achieve its intended use without affecting the flow of the drug solutions into the body. Another difference is the green color of the plunger. Biocompatibility testing were performed, and the green plunger is biocompatible. Therefore, these features do not raise additional questions of safety and effectiveness, hence, it will not affect substantial equivalence between the subject device and predicate device.

8. Non-clinical testing

Performance Testing

The Greenmedi Safety Filter Syringe has been designed and successfully tested to meet the applicable requirements outlined in ISO 7886-1 and ISO 7864 (Normative Reference -ISO 6009, ISO 9626, ISO 594).

- ISO 7886-1 (graduated scale, freedom from air and liquid leakage, lubricant, dead space, piston/plunger assembly)
- ISO 7864:2016 (color coding (ISO 6009), conical fitting (ISO 594), bond between hub and needle, patency of lumen, stiffness (ISO 9626), resistance to breakage (ISO 9626), resistance to corrosion (ISO 9626), simulated use testing (see below)

Simulated Use Testing

Simulated use test was conducted with intended users according to ISO 23908 and the FDA Guidance, "Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff". The simulated test results demonstrated that the GreenMedi Safety Filter syringe's sharps injury prevention feature functions for its intended use.

Biocompatibility Testing

The Greenmedi Safety Filter Syringe has successfully passed testing as outlined in ISO10993-1 for devices categorized as External communicating devices, Limited exposure.

- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10: 2010 Biological evaluation of medical devices Part 10: Test for Irritation and Sensitization 5.4 Intracutaneous reactivity test
- ISO 10993-10 2010 Biological evaluation of medical devices Part 10: Test for Irritation and Sensitization 6.2 Maximization sensitization test
- ISO 10993-11 2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity 6.5 Acute systemic toxicity
- ISO 10993-4:2002 Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood.
- The United States Pharmacopeia <151> (Pyrogen test)
- USP 39-NF34:2016, <151> Pyrogen Test (USP Rabbit Test). (Biocompatibility)

Sterilization and Shelf-life Testing

The sterilization of the Greenmedi Safety Filter Syringe has been validated using the half-cycle method as outlined in ISO11135. The maximum levels of residues of ethylene oxide and ethylene chlorohydrins do not exceed the limits presented in ISO10993-7. Shelf-life testing supports a shelf-life of 5-years after sterilization.

Conclusion

Based on the information provided in this premarket notification of SANG-A FRONTEC CO., LTD. concludes that the Greenmedi Safety Filter Syringe is substantially equivalent to predicate devices.