February 13, 2023

Hwajin Medical Co.,Ltd.
Jeon Hun
Q.m.r
20, Seongsimwon-gil, Seongnam-myeon, Dongnam-gu
Cheonan-si, Chungcheongnam-do 31244
Korea, South

Re: K212635
Trade/Device Name: Sofjec
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG, FMI
Dated: January 11, 2023
Received: January 13, 2023

Dear Jeon Hun:

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/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 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 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,

Alan M. Stevens -S3

CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212635

Device Name
Sofjec

Indications for Use *(Describe)*

Single use Needle
Single use Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

Single use Syringe with Needle
Single use Syringe with Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

Membrane Filter Syringe
Membrane Filter Syringe is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. The 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.

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K212635- 510(k) Summary

1. Date Prepared

February 13, 2023

2. Submitter's Information & Contact Person

- Name of Manufacturer: HWAJIN MEDICAL CO., LTD.
- Address: 20, Seonsimwon-gil, Seongnam-myeon, Dongnam-gu, Cheonan-si, Chungcheongnam-do, 31244, Republic of Korea
- Contact Name: Jeon Sung Hun/Q.M.R
- Telephone No.: +82-41-554-6181
- Fax No.: +82-41-554-7178
- Email Address: sh-jeon@hwajinmedical.com

3. Trade Name, Common Name, Classification

Common name: Syringe, Piston
Trade name: Sofjec

Classification Description	21 CFR Section	Product Code	Class
Syringe, Piston	880.5860	FMF	II
Syringe, Antistick	880.5860	MEG	II
Needle, Hypodermic, Single Lumen	880.5570	FMI	II

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4. Identification of Predicate Device(s)

The identified predicate devices within this submission are shown as follow:

Predicate device

- K190002 – Sterile Hypodermic Syringe for Single Use, with/without needle, Sterile Insulin Syringe for Single Use, Sterile Hypodermic needle for Single use
- K173743 – Greenmedi Safety Filter Syringe

5. Description of the Device

The device has three model with the following:

① Single use Needle(108 model codes including Sofjec-16-13)
Single use Needle consist of Cap, Needle and Hub and Blister paper. Blister paper function to sustain sterilization of the product. The Cap function to protect the needle. This device is single use. This device is provided EO Sterilization.

Needle length according to gauge of Sofjec

No	Model name	Gauge	Needle length
1	Sofjec-16	16	13,16,19,25,32,38
2	Sofjec-17	17	13,16,19,25,32,38
3	Sofjec-18	18	13,16,19,25,32,38
4	Sofjec-19	19	13,16,19,25,32,38
5	Sofjec-20	20	13,16,19,25,32,38
6	Sofjec-21	21	13,16,19,25,32,38
7	Sofjec-22	22	13,16,19,25,32,38
8	Sofjec-23	23	13,16,19,25,32,38
9	Sofjec-24	24	13,16,19,25,32,38
10	Sofjec-25	25	13,16,19,25,32,38
11	Sofjec-26	26	13,16,19,25,32,38
12	Sofjec-27	27	13,16,19,25,32,38
13	Sofjec-28	28	13,16,19,25,32,38
14	Sofjec-29	29	4,5,6,10,13,16,19,25,32,38
15	Sofjec-30	30	4,5,6,10,13,16,19,25,32,38
16	Sofjec-31	31	4,5,6,10,13,16,19,25,32,38

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② Single use Syringe with Needle (1734 model codes including HJ-1-16G-13)

Single use Syringe with Needle consist of Syringe, Cap, Needle and Hub and Blister paper. Blister paper function to sustain sterilization of the product. The Cap function to protect the needle. This device is single use. This device is provided EO Sterilization and the syringes are two type of Luer Slip and Luer Lock.

These device are injecting the medicine with syringes. This device is finished biocompatibility test and performance test for safety.

③ Membrane Filter Syringe(16 model codes including HJM-18-1)

This devices are consists of membrane filter needle and syringe. Membrane filter needle is attached 0.5nm filtration membrane (Acrylic copolymer material). Syringe is two type. (Luer slip type and Luer lock type)

This device is Filtering with syringes and injection devices of medicine. This device is finished biocompatibility test and performance test for safety.

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6. Indications for Use

Characteristics	**Subject Device** Sofjec Single use Needle, Single use Syringe with needle K212635	**Predicate Device** Sterile Hypodermic Syringe for Single Use with/without Needle, Hypodermic Needle for Single Use K190002	**Secondary Predicate** Greenmedi Safety Filter Syringe K173743
Indication for Use	**Single use Needle** Single use Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration. **Single use Syringe with Needle** Single use Syringe with Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. **Membrane Filter Syringe** Membrane Filter Syringe is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. The filter operates when injecting the drug into the human body to remove foreign substances from the drug solutions.	**Sterile Hypodermic Needle for single use** The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/ aspiration. **Sterile Hypodermic Syringe for Single Use with/without Needle** The Sterile Hypodermic Syringe for Single Use with/without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	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.
Prescription Only or Over the Counter	Prescription Only	Prescription Only	Prescription Only

Same between proposed device and the predicate is applicable.

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7. Determination of Substantial Equivalence

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the Sofjec and the predicate devices:

Table 1. General Comparison of Syringe with Needle.

	Proposed Device	Predicate Device – K190002	SE decision
Indications for Use	**Single use Needle** Single use Needle is intended for use with syringes and injection devices for general purpose fluid injection / aspiration. **Single use Syringe with Needle** Single use Syringe with Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	**Sterile Hypodermic Needle for single use** The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/ aspiration. **Sterile Hypodermic Syringe for Single Use with/without Needle** The Sterile Hypodermic Syringe for Single Use with/without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Same
Operation Mode	For manual use only	For manual use only	Same
Configuration	**Single use Needle** Protective cap, Needle tube, Adhesives, Needle hub **Single use Syringe with Needle** Piston, Plunger, Barrel, (Needle)	**Sterile Hypodermic Needle for single use** Protective cap, Needle tube, Adhesives, Needle hub **Sterile Hypodermic Syringe for Single Use with/without Needle** Piston, Plunger, Barrel, (Needle)	Same
Tip type	Luer Slip, Luer Lock	Luer Slip, Luer Lock	Same
Principle of operation	Normal	Normal	Same
Volume/Sizes	**Single use Needle** 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 ,31(G) **Single use Syringe with Needle** Luer slip: Syringe Volume: 1,2,2.5,3,5,10,20,30,50 (ml)	**Sterile Hypodermic Needle for single use** 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30(G) **Sterile Hypodermic Syringe for Single Use with/without Needle**	Difference

<table>
<tr><th></th><th>Proposed Device</th><th>Predicate Device – K190002</th><th>SE decision</th></tr>
<tr><td></td><td>
<table>
<tr><td>Needle gauge</td><td>16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 ,31 (G)</td></tr>
</table>
<table>
<tr><td colspan="2">Luer Lock</td></tr>
<tr><td>Syringe Volume</td><td>1,2,2.5,3,5,10,20,1G,1W,1B(ml)</td></tr>
<tr><td>Needle gauge</td><td>16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 ,31(G)</td></tr>
</table>
</td><td>
<table>
<tr><td>Luer slip Syringe Volume</td><td>1,2,3,5,10,20,30,35,50,60 (ml)</td></tr>
<tr><td>Luer Lock Syringe Volume</td><td>1,2,3,5,10,20,30,35,50,60 (ml)</td></tr>
<tr><td>Needle gauge</td><td>18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30(G)</td></tr>
</table>
</td><td></td></tr>
<tr><td colspan="4">Different- Syringe Volume and Connector Type
The Syringe volume for proposed device is different from the predicate devices. However, this difference is just in dimension. Different volume device will be selected by physician per patient’s condition. This difference does not affect intended use. Moreover, the syringe volume of the proposed syringe is covered by the range of the syringe volume of the predicate device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.</td></tr>
<tr><td>Needle Lengths</td><td>4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)</td><td>4-38mm</td><td>Difference</td></tr>
<tr><td colspan="4">Different-Needle Size and Length
The needle size and length for proposed device is different from the predicate device. However, this difference is just in dimension. Different size and length device will be selected by physician per patient’s condition. This difference does not affect intended use. Moreover, the needle length of the proposed syringe in the range of the needle length of the predicate device. The needle size of the syringe is very close to that of the comparison product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness with the predicate device.</td></tr>
</table>

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<table>
<tr><th></th><th>Proposed Device</th><th>Predicate Device – K190002</th><th>SE decision</th></tr>
<tr><td>Materials</td><td>
Single use Needle
<table>
<tr><th>Part</th><th>Raw material</th></tr>
<tr><td>Protective cap</td><td>PP</td></tr>
<tr><td rowspan="2">Hub</td><td>PP</td></tr>
<tr><td>Pigment</td></tr>
<tr><td>Needle</td><td>Stainless Steel (SUS 304L)</td></tr>
<tr><td>Silicone</td><td>Polydimethylsiloxane</td></tr>
</table>
Single use Syringe with Needle
<table>
<tr><td>Barrel</td><td>Polypropylene (PP)</td></tr>
<tr><td>Gasket</td><td>Thermoplastic elastomer</td></tr>
<tr><td rowspan="2">Plunger</td><td>Polypropylene (PP)</td></tr>
<tr><td>Pigment</td></tr>
<tr><td>Silicone</td><td>Polydimethylsiloxane</td></tr>
<tr><td>Adhesives</td><td>Epoxy Resin</td></tr>
</table>
</td><td>
Sterile Hypodermic Needle for single use
<table>
<tr><th>Part</th><th>Raw material</th></tr>
<tr><td>Piston</td><td>Isoprene Rubber</td></tr>
<tr><td>Barrel</td><td>PP</td></tr>
<tr><td>Plunger</td><td>PP</td></tr>
<tr><td>Needle Cover</td><td>PP</td></tr>
<tr><td>Needle</td><td>Stainless Steel (SUS304)</td></tr>
<tr><td>End Cap</td><td>PP</td></tr>
</table>
Sterile Hypodermic Syringe for Single Use with/without Needle
<table>
<tr><th>Part</th><th>Raw material</th></tr>
<tr><td>Protective cap</td><td>PP</td></tr>
<tr><td>Needle tube</td><td>Stainless steel (SUS304)</td></tr>
<tr><td>Adhesives</td><td>Epoxy resin</td></tr>
<tr><td>Needle hub</td><td>PP</td></tr>
</table>
</td><td>Different</td></tr>
<tr><td colspan="4">The differences between the subject device and the predicate are the following
The color of the plunger is pink color. The difference does not affect substantially equivalence on safety and effectiveness with the predicate.</td></tr>
<tr><td>Sterilization method and SAL</td><td>Sterilized by ethylene oxide gas SAL = 10^{-6}</td><td>Sterilized by ethylene oxide gas SAL = 10^{-6}</td><td>Same</td></tr>
<tr><td>Product performance</td><td>Complied with
ISO 7886-1
ISO 7864
ISO 9626</td><td>Complied with
ISO 7886-1
ISO 7864
ISO 9626</td><td>Same</td></tr>
</table>

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Table 2. General Comparison of Filter Syringe

	Proposed Device	Predicate Device – K173743	SE decision
Indications for Use	**Membrane Filter Syringe** Membrane Filter Syringe is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. The 0.5nm filter operates when injecting the drug into the human body to remove foreign substances from the drug solutions.	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.	Same
Operation Mode	For manual use only	For manual use only	Same
Configuration	**Membrane Filter Syringe** Needle, Protective cap, Filter, Bushing, Syringe (Barrel, Gasket, Plunger)	Needle, Lubricant For needle, Hub, Protective Cap, Barrel, Lubricant For barrel, Plunger, Gasket, Filter, Check valve	Different
Different-Configuration The configuration of proposed syringe with needle is similar as predicate device, considering the needle may become disengaged from the syringe when activating the shield for the syringe with luer-slip connector, therefore the proposed syringe doesn't have the configuration of barrel with check valve. We think the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.			
Principle of operation	Normal	Normal	Same
Volume/Sizes	**Membrane Filter Syringe** Luer slip: 1,2,2.5,3,5,10,20,30,50(ml) Luer Lock: 1,2,2.5,3,5,10,20,50(ml) 18G Only	2ml, 3ml, 5ml, 10ml 23G	Difference
Different- Syringe Volume and Connector Type The Syringe volume for proposed device is different from the predicate devices. However, this difference is just in dimension. Different volume device will be selected by physician per patient's condition. This difference does not affect intended use. Moreover, the syringe volume of the proposed syringe with covered by the range of the syringe volume of the predicate device. Therefore, this difference does not affect needle is substantially equivalence on safety and effectiveness.			
Needle Lengths	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	17mm	Difference
Different-Needle Size and Length The needle size and length for proposed device is different from the predicate device. However, this difference is just in dimension. Different size and length device will be selected by physician per patient's condition. This difference does not affect intended use. Moreover, the needle length of the proposed syringe in the range of the needle length of the predicate device. The needle size of the syringe is very close to that of the comparison product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness with the predicate device.			

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<table>
<tr><th></th><th>Proposed Device</th><th>Predicate Device – K173743</th><th>SE decision</th></tr>
<tr><td>Materials</td><td>Membrane Filter Syringe<table><tr><td>Cover</td><td>Polypropylene (PP)</td></tr><tr><td rowspan="2">Hub</td><td>Polypropylene (PP)</td></tr><tr><td>Pigment</td></tr><tr><td>Filter</td><td>Membrane (Polydimethylsiloxane)</td></tr><tr><td>Plunger</td><td>Polypropylene (Pink)</td></tr><tr><td>Gasket</td><td>Thermoplastic elastomer</td></tr></table></td><td><table><tr><th>Part</th><th>Raw material</th></tr><tr><td>Needle</td><td>STS304</td></tr><tr><td>Lubricant For needle</td><td>Silicone Oil</td></tr><tr><td>Hub</td><td>Polypropylene</td></tr><tr><td>Protective cap</td><td>Polypropylene</td></tr><tr><td>Barrel</td><td>Polypropylene</td></tr><tr><td>Lubricant For barrel</td><td>Silicone Oil</td></tr><tr><td>Plunger</td><td>Polypropylene (green)</td></tr><tr><td>Gasket</td><td>Thermoplastic elastomer</td></tr><tr><td>Filter</td><td>Membrane</td></tr><tr><td>Check valve</td><td>Silicon</td></tr></table></td><td>Different</td></tr>
<tr><td colspan="4">The differences between the subject device and the predicate are the following
The color of the plunger is pink color. The difference does not affect substantially equivalence on safety and effectiveness.</td></tr>
<tr><td>Filter spec.</td><td>Membrane Filter Syringe
0.5nm</td><td>5μm</td><td>Different</td></tr>
<tr><td colspan="4">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. Different does not affect intended use. It is only different the filter spec.</td></tr>
<tr><td>Sterilization method and SAL</td><td>Sterilized by ethylene oxide gas SAL = 10^{-6}</td><td>Sterilized by ethylene oxide gas SAL = 10^{-6}</td><td>Same</td></tr>
<tr><td>Product performance</td><td>Complied with
ISO 7886-1
ISO 7864
ISO 9626</td><td>Complied with
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Non-Clinical Test Summary

1) Biocompatibility Test

The devices were tested for biocompatibility per ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Result of evaluation test for consideration

Category: External communicating device
Contact: Blood path, Indirect
Contact duration: A-Limited (≤24)
Test item:

- Cytotoxicity
- In vitro hemolysis
- Skin Sensitization
- Pyrogen
- Acute Toxicity
- Intracutaneous reactivity

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injection and met the USP acceptance criteria.

2) Performance Test

- ISO 7864:2016 Sterile hypodermic needles for single use
- ISO 7886-1:2017 Sterile Hypodermic Syringes For Single Use
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices
- ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications

3) Sterilization, Shelf-life Testing and Simulated Shipping

- Shelf-life test for 3years: ASTM F1980:2002 Standard Guide for Accelerated Aging of Sterile medical device packages
- Ethylene Oxide Sterilization Validation Test: EN ISO11135:2014 Sterilization of medical devices- Validation and routine control of sterilization by ethylene oxide sterilization.
- Ethylene oxide gas residual test : ISO10993-7:2008 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- Pyrogen Test: Endotoxin: USP 39, <85> Bacterial Endotoxins Tests, USP 45, <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests
- ISTA 2017 Integrity Test Procedure 2A: Simulated transportation test

Clinical Test Summary

No clinical studies were considered necessary and performed.

8. Conclusion

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance testing demonstrates that the subject device is substantially equivalent to the legally marketed predicate device.