December 23, 2024

HLB LifeScience Co., Ltd.
% Yongjun Lee
Consultant
MEDIGUIDE Inc.
#410, 17, Deogan-ro 104beon-gil, Gwangmyeong-si
Gyeonggi-do, 14353
Korea, South

Re: K241856
Trade/Device Name: Sofjec (Single use Needle); Sofjec (Single use Syringe with or without Needle); Sofjec (Membrane Filter Syringe)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: June 27, 2024
Received: December 3, 2024

Dear Yongjun Lee:

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
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: 07/31/2026
See *PRA Statement below.*

Submission Number *(if known)*

K241856

Device Name

Sofjec (Single use Needle);
Sofjec (Single use Syringe with or without Needle);
Sofjec (Membrane Filter Syringe)

Indications for Use *(Describe)*

Single use Needle(108 model codes including Sofjec-16-13)
Single use Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

Single use Syringe with or without Needle (2186 model codes including HJ-1-16G-13)
Single use Syringe with or without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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122-39, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, Republic of Korea
Tel: +82 (41) 554 6181 Fax: +82 (41) 554 7178

510(k) Summary

Date of Preparation: December 23, 2024

Subject: "Special 510(k) Premarket Notification" for Sofjec – Device Modification.

Model: Single use Syringe with or without Needle (2186 model codes including HJ-1-16G-13)

Applicant Information:

- Manufacturer: HLB Life Science Co., Ltd.
- Address: 122-39, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, Republic of Korea
- Tel: +82 (41) 554 6181
- Fax: +82 (41) 554 7178
- Manufacturer Contact: JiWon Han (hlblsra@hlb-ls.com)

510(k) Correspondent:

Yongjun Lee, Consultant of MEDIGUIDE Inc.

guide33@medi-guide.com / Tel: +82 (70) 5057 6201

Identification of Predicate Device

Trade Name	Subject Device Special 510(k) No.	Predicate Device 510(k) No.
Sofjec	K241856	K212635

Device name and Classification name

- Trade Name: Sofjec (Single use Needle); Sofjec (Single use Syringe with or without Needle); Sofjec (Membrane Filter Syringe)
- Model:
  - ① Single use Needle(108 model codes including Sofjec-16-13)
  - ② Single use Syringe with or without Needle (2186 model codes including HJ-1-16G-13)
  - ③ Membrane Filter Syringe (16 model codes including HJM-18-1)

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

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Reason for Submission

HLB Life Science Co., Ltd. hereby submits this Special 510(k) to provide notification of modification to:

- Hwajin Medical Co., Ltd., Sofjec Piston Syringe K212635

This Special 510(k) has been submitted to change the "Single use Syringe with Needle (1734 model codes including HJ-1-16G-13) in primary predicate device (K212635) to "Single use Syringe with or without Needle (2186 model codes including HJ-1-16G-13).

Modification to this piston syringe includes:

- Basic Change: Additional Syringe model with 60 (mL) to existing HJ/HJL series of 1, 2, 2.5, 3, 5, 10, 20, 30, 50 (mL)
- Additional Change: Additional Syringe model without Needle for HJ/HJL-x WO series to existing HJK/HJKL-x series.

Indication for Use

① Single use Needle (108 model codes including Sofjec-16-13)
Single use Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

② Single use Syringe with or without Needle (2186 model codes including HJ-1-16G-13)
Single use Syringe with or without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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

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Device Description

Single use Syringe with or without Needle

Single use Syringe with or without 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 types of Luer Slip and Luer Lock.

These devices are injecting the medicine with syringes. Biocompatibility testing and performance testing has been completed to support the substantial equivalence of the device.

Additional Model List for the subject Special 510(k)

In this special 510(k) submission, a new volume (60mL) of syringe luer slip/luer lock with or without needle is covered. The intended use, raw material, manufacturing site, sterilization method, sterilization site, packaging material is the same as the devices cleared in K212635. The table below describes the additional model for this Special 510(k) submission.

Syringe Volume	Gauge	Length	Luer Type	Approval No.
1 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	K212635
			Luer Lock	
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
2 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	K212635
			Luer Lock	
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
2.5 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	K212635
			Luer Lock	
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
3 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	K212635
			Luer Lock	
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
5 mL			Luer Slip	K212635

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Syringe Volume	Gauge	Length	Luer Type	Approval No.
	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Lock	
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
10 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip Luer Lock	K212635
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
20 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	K212635
			Luer Lock	
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
30 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	K212635
			Luer Lock	Current Submission
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
50 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	K212635
			Luer Lock	Current Submission
	Without Needle		Luer Slip	Current Submission
			Luer Lock	
60 mL	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Luer Slip	Current Submission
			Luer Lock	
	Without Needle		Luer Slip	Current Submission
			Luer Lock	

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Comparison table of Modified Device and Predicate Device

<table>
<tr><th>Item</th><th>Modified Device
Single use Syringe with or without Needle</th><th>Primary Predicate Device
Single use Syringe with Needle (K212635)</th><th>SE decision</th></tr>
<tr><td>Indications for Use</td><td>Single use Syringe with or without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.</td><td>Single use Syringe with Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.</td><td>Difference</td></tr>
<tr><td colspan="4">Difference
- Additional syringe model with 60 (mL) to existing HJ/HJL series of 1, 2, 2.5, 3, 5, 10, 20, 30, 50 (mL)
The dimension of the 60mL syringe is identical with 50mL syringe in K212635. The only difference between 60mL syringe (modified device) and 50mL syringe (predicate device) is scale depicted on the barrel of the syringe. The performance tests covered the 50ml syringe in the cleared K212635 can be leveraged for the proposed 60ml syringe.

- Addition of single use syringe without needle
The model of single use syringe without needle [HJ/HJL-x WO of 1, 2, 2.5, 3, 5, 10, 20, 30, 50, 60 (mL)] are added in the existing HJK/HJKL-x series of the Single use Syringe with Needle (K212635). The dimension, raw material, technological characteristics of the additional models are same with the Single use Syringe with needle.</td></tr>
<tr><td>Operation Mode</td><td>For manual use only</td><td>For manual use only</td><td>Same</td></tr>
<tr><td>Configuration</td><td>Piston, Plunger, Barrel, (Needle)</td><td>Piston, Plunger, Barrel, (Needle)</td><td>Same</td></tr>
<tr><td>Tip type</td><td>Luer Slip, Luer Lock</td><td>Luer Slip, Luer Lock</td><td>Same</td></tr>
<tr><td>Principle of operation</td><td>Normal</td><td>Normal</td><td>Same</td></tr>
<tr><td>Volume/Sizes</td><td>Luer slip
Syringe Volume: 1, 2, 2.5, 3, 5, 10, 20, 30, 50, 60 (ml)
Needle gauge: 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 ,31 (G)

Luer Lock
Syringe Volume: 1, 2, 2.5, 3, 5, 10, 20, 30, 50, 60, 1G, 1W, 1B (ml)
Needle gauge: 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 ,31(G)</td><td>Luer slip
Syringe Volume: 1, 2, 2.5, 3, 5, 10, 20, 30, 50 (ml)
Needle gauge: 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 ,31 (G)

Luer Lock
Syringe Volume: 1, 2, 2.5, 3, 5, 10, 20, 1G, 1W, 1B (ml)
Needle gauge: 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 ,31(G)</td><td>Difference</td></tr>
<tr><td colspan="4">Different- Syringe Volume
The Syringe volume of modified device is different from the primary predicate devices(K212635). However, this difference is just in volume. The physical dimension of the 60mL syringe is the same as the 50mL syringe. The scale depicted on the barrel of the syringe is different. This difference does not affect the devices intended use. Successful performance testing has been completed using FDA recognized standards to support that this difference in syringe volume does not raise new or different questions of safety and effectiveness when compared to the predicate device.</td></tr>
<tr><td>Needle Lengths</td><td>4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)</td><td>4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)</td><td>Same</td></tr>
</table>

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<table>
<tr><th>Item</th><th>Modified Device
Single use Syringe with or without Needle</th><th>Primary Predicate Device
Single use Syringe with Needle (K212635)</th><th>SE decision</th></tr>
<tr><td>Materials</td><td>Single use Syringe with or without Needle
<table>
<tr><th>Part</th><th>Raw material</th></tr>
<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>
<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></td><td>Single use Syringe with Needle
<table>
<tr><th>Part</th><th>Raw material</th></tr>
<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>
<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></td><td>Same</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>

Conclusion

The difference between the cleared (predicate) and the modified device do not raise any new or different questions of safety and effectiveness since the modified devices are tested in accordance with the ISO 7886 -1 standard. The subject devices are substantially equivalent to the predicate devices with respect to the indications for use, target populations, treatment method, and technological characteristics.