May 21, 2026

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

Re: K253112
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, QNQ, FMI
Dated: September 24, 2025
Received: April 22, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K253112

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 (114 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 (2816 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.

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K253112 510(k) Summary

Date of Preparation: May 21. 2026

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

a. Applicant Information:

Applicant, 510(k) Owner	:	HLB Life Science Co., Ltd. 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 MEDIGUIDE Inc. guide33@medi-guide.com Tel: +82 (10) 9963 3680

b. 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 (114 model codes including Sofjec-16-13)
  - ② Single use Syringe with or without Needle (2816 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
Low Dead Space Piston Syringe	880.5860	QNQ	II
Needle, Hypodermic, Single Lumen	880.5570	FMI	II

c. Identification of Predicate Device

K No.	Device Name	Remark
K241856	Sofjec (Single use Needle), Sofjec (Single use Syringe with or without Needle), Sofjec (Membrane Filter Syringe)	Primary Predicate Device
K232943	Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe	Reference Predicate Device #1
K233037	Sterile Hypodermic Needles for Single use	Reference Predicate Device #2

d. Indication for Use

① Single use Needle (114 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 (2816 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.

e. Device Description

① **Single use Needle**

The Single use Needle is a sterile, disposable medical device intended for use by healthcare professionals (e.g., physicians, nurses, pharmacists) in clinical settings such as hospitals, and clinics for the injection of medicines or other pharmaceutical solutions and for the aspiration of body fluids. The device consists of a needle, hub, and cap. The device is packaged by blister paper to maintain sterility. All components are supplied sterile by ethylene oxide (EO) sterilization prior to use.

② **Single use Syringe with or without Needle**

The Single use Syringe with or without Needle is a sterile, disposable medical device intended for use by healthcare professionals (e.g., physicians, nurses, pharmacists) in clinical settings such as hospitals, and clinics for the injection of medicines or other pharmaceutical solutions and for the aspiration of body fluids. When supplied with a needle, the device consists of a syringe, needle, hub and cap. When supplied without a needle, it consists of the single use syringe only. The blister paper maintains the sterility of the product. The Low Dead Space (LDS) Syringe – new component – is added to form new device combination with the preciously cleared Single use Syringe with or without Needle. The LDS Syringe is intended to reduce the amount of medical product remaining in the needle's hub and the syringe's tip after injection. The syringes

are available in Luer Slip, and Luer Lock. All devices are supplied sterile by ethylene oxide (EO) sterilization prior to use. The device is intended for single use only.

③ **Membrane Filter Syringe**

The Membrane Filter Syringe is a sterile, disposable medical device intended for use by healthcare professionals (e.g., physicians, nurses, pharmacists) in clinical settings such as hospitals, and clinics for the injection of medicines or other pharmaceutical solutions and for the aspiration of body fluids. The device consists of a membrane filter needle and a syringe. The syringes are available in two types: Luer Lock and Luer Slip. The Membrane filter needle incorporates a 0.5 nm filtration membrane made of acrylic copolymer material. The devices are used for filtering syringes and for injection of medicines. All devices are supplied sterile by ethylene oxide (EO) sterilization prior to use. The device is intended for single use only.

h. Comparison table of Modified Device and Predicate Device

Item	**Modified Device**	**Primary Predicate Device** K241856	Comment
General			
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 or without Needle 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 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.	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 or without Needle 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 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.	Identical to primary predicate
Product Code	FMF, QNQ, FMI	FMF, FMI	Difference #1
Regulation Number	21 CFR 880.5860 21 CFR 880.5570	21 CFR 880.5860 21 CFR 880.5570	Identical to primary predicate
Single Use	Yes	Yes	Same
Prescription only	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sofjec – Single use Syringe with or without Needle			
Configuration	Plunger, Barrel, Gasket, (Needle)	Plunger, Barrel, Gasket, (Needle)	Identical to primary predicate
Tip type	Luer Slip, Luer Lock	Luer Slip, Luer Lock	Identical to predicate device
Syringe Volume	Luer Slip 1, 2, 2.5, 3, 5, 10, 20, 30, 50, 60 (mL)	Luer Slip 1, 2, 2.5, 3, 5, 10, 20, 30, 50, 60 (mL)	Identical to predicate device
	Luer Lock 1, 2, 2.5, 3, 5, 10, 20, 30, 50, 60, 1G, 1W, 1B (mL)	Luer Lock 1, 2, 2.5, 3, 5, 10, 20, 30, 50, 60, 1G, 1W, 1B (mL)	

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Needle Gauge	14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	Difference #2
Needle Length	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Identical to predicate device
Material	**Syringe** Barrel: PP Gasket: Thermoplastic elastomer Plunger: PP and Pigment Silicone: Polydimethylsiloxane Adhesive: Epoxy Resin Tip Cap: PP and pigment **Needle** Protective cap: PP Hub: PP and Pigment Needle: Stainless Steel (SUS 304L) Silicone: Polydimethylsiloxane	**Syringe** Barrel: PP Gasket: Thermoplastic elastomer Plunger: PP and Pigment Silicone: Polydimethylsiloxane Adhesive: Epoxy Resin **Needle** Protective cap: PP Hub: PP and Pigment Needle: Stainless Steel (SUS 304L) Silicone: Polydimethylsiloxane	Difference #3
Syringe Dead Space Volume	≤ 0.070 mL for standard type syringe ≤ 0.035 mL for LDS type syringe	≤ 0.070 mL	Difference #1
Sofjec – Single use Needle			
Needle Gauge	14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 (G)	Difference #2
Needle Length	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	4, 5, 6, 10, 13, 16, 19, 25, 32, 38 (mm)	Identical to predicate device
Material	**Needle** Protective cap: PP Hub: PP and Pigment Needle: Stainless Steel (SUS 304L) Silicone: Polydimethylsiloxane	**Needle** Protective cap: PP Hub: PP and Pigment Needle: Stainless Steel (SUS 304L) Silicone: Polydimethylsiloxane	Identical to predicate device

Difference #1 : The modification introduces a 1 mL Low Dead Space (LDS) Syringe variant (Product code: QNQ) in addition to the existing 1 mL standard type syringe cleared under K241856, except for gasket geometry. All other aspects – including barrel and plunger dimensions, materials, manufacturing processes, sterilization method, and performance requirements – remain unchanged. The only change is the gasket shape, which reduces residual fluid volume from ≤ 0.070 mL to ≤ 0.035 mL, without altering intended use or the fundamental principle of operations. Design verification testing performed in accordance with ISO 7886-1 confirmed that the LDS variant meets all acceptance criteria for leakage, plunger movement, nozzle fit, and fluid delivery accuracy. This change does not introduce any new questions of safety or effectiveness when compared to the predicate device as mechanical integrity, biocompatibility, and sterilization assurance remain unchanged. Additionally, the LDS configuration with similar performance has been legally marketed (Ref. K232943).

Difference #2 : The expanded needle gauge range includes an additional size (14G Needle), which has been incorporated into the Predicate Device series for both the *Single Use Syringe with Needle* and *Standalone Needle* configurations. This gauge size is already legally marketed, as demonstrated by Reference Device (K233037). All other design features – including needle material, bevel type, hub configuration, manufacturing process, and sterilization method – remain identical to those of the cleared predicate device (K241856). The addition of these gauges does not introduce new safety risks, as mechanical strength, connection integrity, and lumen patency are maintained through the same design and manufacturing controls applied to the predicate range. There is no impact on device effectiveness, since the fundamental performance characteristics for fluid injection/aspiration remain unchanged. Therefore, this modification does not raise new questions of safety or effectiveness when compared to the predicate device and supports substantial equivalence to the predicate device (K241856).

Difference #3	:	The subject device includes a modification in which the tip cap and plunger of the syringe (without needle) are manufactured using polypropylene (PP) with added pigment for coloring. This modification does not alter the device's indications for use, mode of operation, or fundamental scientific technology. The colored components serve only as protective and user-recognition features and do not contact the fluid pathway. Biocompatibility and performance evaluations conducted on the material with pigment confirmed that the modification does not adversely affect the safety or effectiveness of the device when compared to the predicate. Therefore, the difference in colored tip cap and plunger does not raise new questions of safety or effectiveness when compared to the predicate device.

i. Performance Data

1 mL Low Dead Space Syringe

Performance testing was conducted to verify and validate that the addition of the Low Dead Space (LDS) syringe to the subject device family does not adversely affect safety or performance. In-house bench tests were performed in accordance with ISO 7886-1:2017 requirements, including dimensional verification, residual volume test, and liquid leakage test.

- Dimensional verification confirmed all measured parameters (outer diameter, length, plunger dimensions, and needle gauge) were within specified tolerances.
- Residual volume test showed all tested samples met the acceptance criterion of ≤ 0.035 mL per ISO 7886-1 Annex D.
- Liquid leakage test confirmed no water leakage in any sample, and all samples complied with residual volume limits.

14G Needle

Performance testing was conducted to verify and validate that the addition of 14G Needle to the subject device family does not adversely affect safety or performance. In-house bench tests were performed in accordance with ISO 7864:2016 and ISO 9626:2016 requirements, including dimensional verification, and performance tests.

- Dimensional verification confirmed all measured parameters (needle length, gauge, and diameter of tubing) were within specified tolerances.
- Bond between hub and needle tube test showed all tested samples met the minimum acceptance criterion.
- Stiffness test demonstrated the tubing met the minimum stiffness requirements as defined for the 14 G Needle.

The results demonstrate that the LDS syringe and 14G needle meet the applicable ISO 7886-1, ISO 7864, and ISO 9626 performance criteria and is substantially equivalent in safety and effectiveness to the predicate device.

j. Conclusion

The verification and validation activities confirm that the design modification involving the addition of the LDS syringe and 14G needle does not negatively impact device performance or safety. All tested parameters met the predetermined acceptance criteria, demonstrating compliance with ISO 7886-1:2017, ISO 7864:2016, and ISO 9626:2016. Therefore, the modified devices are as safe and effective as the predicate device and are substantially equivalent to the predicate.