January 12, 2024

SMB Corporation of India
% Atonu Datta, CEO
Alceon Medtech Consulting
1008, 10th Floor, "OCEAN", Sarabhai Compound
Near Centre Square mall, Dr. V.S. Marg
Vadodara, Gujarat 390023, India

Re: K231558
Trade/Device Name: SMB Luer lock disposable syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: December 5, 2023
Received: December 11, 2023

Dear Atonu Datta:

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.

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
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General Hospital, and Urology Devices
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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)*
K231558

Device Name
SMB Luer lock disposable syringe

Indications for Use *(Describe)*
SMB Hypodermic Syringe is used to inject fluid into or withdraw fluid from the body. This device is for single use only.

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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3. Date of preparing the summary

01/05/2024

4. Device Details

Device name (Generic):	Hypodermic Syringe with Needle
Device name (Trade Name):	SMB Luer lock disposable syringe
Classification Regulation:	21 CFR 880.5860, 21 CFR 880.5570
Device Class:	Class II
Product Code:	FMF, FMI
Panel:	General hospital

5. Predicate Device

Subject Device Manufacturer	Subject Device	Primary Predicate Device 510K	Secondary Predicate Device 510K
SMB Corporation of India	Sterile, Single use Hypodermic Syringe With needle	K202432	K102584 (For Needle)

6. Device Description

The SMB Luer lock disposable syringe is a standard Piston Syringe. It is a two-piece Syringe with male 6% luer lock connection. The Syringe is supplied with Hypodermic Needle having a female 6% luer hub. The Syringe and Needle are supplied sterile and sterilized by ETO gas. The device is single use device and non-pyrogenic. The device is available with 2ml Syringe and 23G Needle.

A detailed description of Syringe and Needle is as follows:

Syringe: The Syringe consists of hollow barrel with graduated scale and movable plunger. The barrel has a nozzle with a male luer lock connector that facilitates the connection with female luer lock hub of needle. The graduated scale on the barrel is indicated in the milliliters. The movable plunger is pulled to aspirate and pushed to inject the fluids into barrel.

Needle: The Needle consists of Needle tube, Needle hub, Needle cap. The Needle tube is attached to the Needle hub and the Needle hub is attached to the syringe by luer lock system. A cap is provided to protect Needle sharps protection as well as prevention of injury.

The materials used in manufacturing of Syringe & Needle are safe as demonstrated by the biocompatibility study performed for biological evaluation. Table 1 gives information about raw material.

Table: 1 Raw Material

Components	Material	Grade	CAS No.	Type of Body Contact
Barrel	Polypropylene	RF830MO	9010-79-1	In direct contact with blood path
Plunger	HDPE	EHM 6007	9002-88-4	In direct contact with blood path

Components	Material	Grade	CAS No.	Type of Body Contact
Needle tube	Stainless steel	SS304	N/A	Direct contact with blood path
Needle hub	Polypropylene (Deep Blue colour)	RF830MO	9010-79-1	In direct contact with blood path
Needle cover	HDPE	EHM 6007	9002-88-4	No contact

Indication for use:

SMB Hypodermic Syringe is used to inject fluid into or withdraw fluid from the body. This device is for single use only.

7. Comparison to a predicate device

1. Comparison of Syringe to Predicate Device

Description	Subject Device (Applied)	Primary Predicate Device (K202432)	Comparison
Trade/Device Name	SMB Luer lock disposable syringe	MiniLoad Syringe	-
Manufacturer	SMB Corporation of India	OcuJect, LLC	-
510 (K)	Applied	K202432	-
Class	Class II	Class II	Same
Regulatory number	21 CFR Part 880.5860	21 CFR Part 880.5860	Same
Product code	FMF	FMF	Same
Syringe type	Piston Syringe	Piston Syringe	Same
Indication for use	SMB Hypodermic Syringe is device that is used to inject fluid into or withdraw fluid from the body. This device is used for single use only.	The MiniLoad Syringe is used to facilitate injections into or withdraw fluids from body.	Same
Configuration	Barrel Plunger	Barrel Plunger	Same
Materials			

Description	Subject Device (Applied)	Primary Predicate Device (K202432)	Comparison
Barrel	Polypropylene	Polypropylene	**Different 1**
Plunger	Polyethylene	Polyethylene	
Lubricant	Silicone oil	Oleamide	
Principle of operation	Piston Syringe	Piston Syringe	Same
Technical specification			
Barrel Length	62 ±5mm	~85 mm	**Different 2**
Barrel Diameter	10.30 ±0.10mm	~6.4 mm	**Different 3**
Barrel Size (Volume)	2 ml	1 ml	**Different 4**
Plunger Length	64 ±5mm	93.4	**Different 5**
Nozzle type	Luer-lock	Slip Tip	**Different 6**
Graduation	Printed, ISO 7886-1 compliant	Printed, ISO 7886-1 compliant	Same
Barrel transparency	Transparent (Fluid & scale marking clearly visible)	Transparent	Same
Reuse durability	Single use only	Single use only	Same
Sterilization Method	EO	EO	Same
SAL	10^6	10^6	Same
Biocompatibility	1. Cytotoxicity 2. Sensitization 3. Irritation or Intracutaneous reactivity 4. Acute systemic toxicity 5. Material mediated pyrogenicity 6. Hemocompatibility	1. Cytotoxicity 2. Sensitization 3. Irritation or Intracutaneous reactivity 4. Acute systemic toxicity 5. Material mediated pyrogenicity 6. Hemocompatibility	Same
Particulate Contamination	Met the USP<788>	Met the USP<788>	Same
Label/Labelling	Conform with 21 CFR 801	Conform with 21 CFR 801	Same
Shelf Life	5 years	5 Years	Same

2. Comparison of Needle to Predicate Device

Description	Subject Device (Applied)	Secondary Predicate Device (K102584)	Comparison
Class	Class II	Class II	Same
Regulatory number	21 CFR Part 880.5570	21 CFR Part 880.5570	Same
Product code	FMI	FMI	Same
Configuration	Needle Hub Needle Needle Cover	Needle Hub Needle Needle Cover	Same
Materials			
Needle Hub	Polypropylene	Polypropylene	**Different 7**
Needle	S.S 304	S.S 304	
Needle Cover	HDPE	Polypropylene	
Technical specification			
Needle gauge	23 G	16 G to 30 G	Same- (Predicate device have some additional gauge sizes)
Nozzle type	Luer-lock	Luer-lock/ Luer-Slip	Same- (Predicate device have additional nozzle type)
Needle cover color	Transparent	Transparent	Same
Hub/needle bond strength	Complies as per ISO 7864:2016	Complies as per ISO 7864:2016	Same

Summary of Substantial Equivalence:

Different 1, 7:

The subject and predicate devices contain a similar generic class of materials. However, the exact material grade of the predicate device is not publicly available. There may also be differences in manufacturing and processing aids that may result in a different finished material. Therefore, testing per ISO 10993 and the FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing

within a risk management process" was performed to assess the biological impact of the finished material.

The results of biocompatibility studies were found satisfactory, and we conclude that the materials do not impact the safety and effectiveness of the subject device compared to the predicate device. Hence, the difference can be considered acceptable.

Different 2, 3, 4, 5:
The intended use of different sizes is the same as the predicate device. The raw material used for the subject device is similar to the predicate device. However, there may be differences in manufacturing and processing that results in a different finished material. Additionally, the device is tested in accordance with the ISO 7886-1:2017, ISO 80369-7:2016, ISO 7864:2016 standards and the results were found satisfactory. Considering these factors, the dimensional difference of barrel & needle does not impact the safety and effectiveness of the subject device when compared to the predicate device. Hence, the difference can be considered acceptable.

Different 6:
The predicate Hypodermic Needle is attached to the Hypodermic Syringe by means of lock or push fit (Slip) style. The subject device is attached by means of Luer-lock system. To address this difference, the subject device is tested in accordance with the ISO 7886-1:2017, ISO 80369-7:2016, ISO 7864:2016 standards and the results were found satisfactory. Considering the above difference, it is concluded that Luer-lock system will not result in liquid leakage and prevents accidental removal of needle. Hence, this difference can be considered acceptable.

For the needle cover, different materials were used for the subject device and predicate devices. Testing per ISO 10993 and the FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" was performed in order to assess the differences in finished material.

The results of biocompatibility were found satisfactory and the material difference does not impact the safety and effectiveness of the subject device when compared to the predicate device. Hence, the difference can be considered acceptable.

8. Summary of non-clinical performance data

Non-clinical tests were conducted to verify that the proposed devices met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

STANDARDS	TEST PARAMETERS
ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods
ISO 9626-2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
ISO 594-1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
ISO 594-2	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
ISO 7886-1:2017	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
USP 32 NF27	Sterility
USP <85>	Bacterial Endotoxin test
USP <788>	Particulate contamination
Biocompatibility	
ISO 10993-11:2021	Acute Systemic toxicity
ISO 10993-5:2009	Cytotoxicity
ISO 10993-10: 2021	Skin sensitization study in guinea pigs
ISO 10993-10: 2021	Intracutaneous reactivity test
USP-39 NF-34, Chapter 151 & ISO 10993-11	Material mediated Pyrogenicity
ISO 10993-4 ISO 10993-4:2017 ASTM F 756-17	Hemocompatibility Test Extract Method Direct Contact Method
Packaging Test:	
ISO 11607-1:2019 2nd edition	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems
ISO 11607-2:2019 2nd edition	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
Sterilization Test:	

STANDARDS	TEST PARAMETERS
ISO 11135:2014/AMD 1:2018 2nd edition	Sterilization of health care products - Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices.
EO Residual Test:	
ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals, and it meets the requirements of the standard.
Bacterial Endotoxin Test:	
USP <85>	The Bacterial endotoxin testing of subject devices was performed by the "**Gel-Clot Method**" and meets the requirement of USP <85>.

9. Summary of clinical performance data

No clinical data is included in this premarket application submission.

10. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.