



March 6, 2024

SPM Medicare Pvt. Ltd.
% Prithul Bom, Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K233794

Trade/Device Name: Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 6, 2024
Received: March 6, 2024

Dear Prithul Bom:

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

Division of Drug Delivery and General

Hospital Devices, and Human Factors

Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233794

Device Name

Insulin Syringe

Indications for Use (Describe)

The sterile Insulin Syringe is for single use, with the calibrated unit of insulin for U-40 & U-100. The Insulin Syringe is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface of the skin. The device is intended to be used for adults 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.

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

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510k Summary **K233794**

This 510k summary is being prepared in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

Device Submitter: SPM Medicare Pvt. Ltd
 B-40, Phase II
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Date of Preparation: February 7, 2024

II. DEVICE

Identification of proposed device:
Trade Name: Insulin syringe
Common name: Insulin syringe

Regulatory Information:

Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

III Predicate Device

1. 510(k) Number K223453
Product Name: Insulin Syringe
Regulation Number: 21 CFR 880.5860
Product Code: FMF

Manufacturer Name:

Promisedmed Hangzhou Meditech Co., Ltd. Zearou
Yang
Regulatory affairs manager
No. 1388, Cangxing Street, Cangqian Community, Yuhang
District, Hangzhou City,
Zhejiang 311121, China

IV: Device Description:

The proposed device, Insulin Syringe, is a sterile device consisting of a calibrated hollow barrel, needle, needle cover and end cap. The Insulin syringe is intended for medical purpose for the manual aspiration of insulin and for the injection of insulin into parts of the body below the surface skin. The device is intended to be used for adults only. The needle is fixed on the syringe. The syringes barrel and plunger is made up of Polypropylene, the gasket is of Thermo Plastic Elastomer (TPE) and the needle cover (Top Cap) and end cap (Bottom Cap) is made up of polypropylene.

Device Range:

The proposed Insulin Syringe will be distinguished on the basis of their size and units. The 1 ml U-40 & U-100 syringes are being manufactured with different needle gauges, U-40 means 40 units of insulin in every Lm and U-100 means there are 100 units of insulin in every mL. The color code is used to identify the strength, where the red cap is used to identify U-40 units & the orange cap is used to identify U-100 units.

Nominal Capacity: 1 ml (U-40), 1 ml (U-100)

S. No.	Gauge	O.D of Needle	Length of Needle
1	28G	0.349 – 0.370 mm	6 mm, 8 mm,12.7mm
2	29G	0.324 – 03.51 mm	6 mm, 8 mm,12.7mm
3	30G	0.298 – 0.320 mm	6 mm, 8 mm,12.7mm
4	31G	0.254 – 0.267 mm	6 mm, 8 mm,12.7mm
5	32G	0.229 – 0.241mm	6 mm, 8 mm,12.7mm

V. INDICATIONS FOR USE

The sterile Insulin Syringe is for single use, with the calibrated unit of insulin for U-40 & U-100. The Insulin Syringe is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface of the skin. The device is intended to be used for adults only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Table 1 Comparison of Technology Characteristics

Item	Proposed Device (K233794)	Predicate Device K223453	Comments
Trade Name	Insulin Syringe	Insulin Syringe	
Manufacturer	SPM Medicare Pvt. Ltd.	Promised Hangzhou Meditech Co., Ltd	
Device Class	Class II	Class II	Same
Product Code	FMF	FMF	Same
Regulation number	880.5860	880.5860	Same
Regulation Name	Piston syringe	Piston syringe	Same
Intended Use/ Indications for Use	The sterile insulin syringe for single use, with the calibrated unit of insulin for U-40 & U-100 is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin. The device is intended to be used for adults only.	Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	Same
Type of use	Prescription use and over the-counter use	Prescription use and over the-counter use	Same
Operating Principle	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe.	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe.	Same
Specific drug use	Insulin	Insulin	Same
Length	118mm	120mm	Different. Proposed device has 118 mm length and predicate device has 120 mm length. This does not impact the intended use of device.
Volume	1.0ml	0.3ml, 0.5ml, 1.0ml	Different Only 1.0ml insulin syringe is included for the subject device

Needle length	6mm, 8mm,12.7mm	6mm, 8mm,12mm	Different. Compared to the predicate device, the proposed device has a difference in needle length. The 12.7mm needle length of the insulin syringe safety and performance has been confirmed by testing. This difference does not raise new question of safety and effectiveness.
Needle gauge	32G, 31G, 30G, 29G, 28G	32G, 31G, 30G, 29G, 28G	Same
Needle tip configuration	3 bevels	3 bevels	Same
Nozzle type	Not applicable	Not applicable	Same
Numbering of scale	At every 10units for 1.0ml	At every five units for the 0.3mL and 0.5mL syringes, and at every 10units for 1.0mL	Same The proposed device has only the 1.0 ml capacity & the predicate device includes a 0.5mL and 0.3ml model. The difference in capacity device will be selected by the physician per the patient's condition. This difference does not affect intended use.
Gradations legibility	Legible	Legible	Same
Needle cover dimensions	Length: 25mm, Diameter: 6mm	Length: 25mm, Diameter: 6mm	Same
Needle cover colour	Red (U-40) and orange (U-100)	Red (U-40) and orange (U-100)	Same
Lubricant composition	Aminofunctional siloxane	Aminofunctional siloxane	Same
Lubricant amount/cm ²	The lubricant does not form pools of fluid on the interior surface of the syringe or outside surfaces of the	The lubricant does not form pools of fluid on the interior surface of the syringe or outside	Same

	needle tube.	surfaces of the needle tube.	
Barrel transparency	Transparent	Transparent	Same
Needle cover strength	<15N	<15N	Same
Hub/needle bond strength	>22N	>22N	Same
Biocompatibility	No Cytotoxicity No irritation reactivity No significant evidence of skin sensitization No significant evidence of systemic toxicity No evidence of Hemolysis	No cytotoxicity No irritation reactivity No significant evidence of skin sensitization No significant evidence of systemic toxicity No evidence of Hemolysis	Same
Configuration and Material	Needle: Stainless Steel (SS304) Barrel: Polypropylene Plunger: Polypropylene Piston: Polyisoprene rubber Needle cap: Polypropylene Protective end cap: Polypropylene	Needle: Stainless Steel (SS304) Barrel: Polypropylene Plunger: Polypropylene Piston: Polyisoprene rubber Needle cap: Polyethylene Protective end cap: Polyethylene	Different. The materials of the needle cap and protective end cap are different between the proposed device and predicate device. The biocompatibility test of the proposed device was conducted to demonstrate that the subject device met the biocompatibility requirements. This difference does not raise any new safety and effectiveness questions.
Label	Brand Name, Device name, indication, instruction for use, precaution, warning, shelf life, manufacturer	Device name, indication, instruction for use, precaution, warning, shelf life, manufacturer	Same
Sterilization method and SAL	Sterilized by ethylene oxide gas SAL = 10 ⁻⁶	Sterilized by ethylene oxide gas SAL = 10 ⁻⁶	Same
Sterilization method	EO Sterilization	EO Sterilization	Same
EO and ECH residues testing	Conform ISO 10993-7	Conform ISO 10993-7	Same

Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.

VII. Performance Data

Performance testing was conducted to ensure the substantial equivalence of the Insulin syringe throughout the shelf life and verify conformity to the applicable parts of ISO standards. No new question of safety and effectiveness were raised with the testing performed on the subject device when compared to the predicate device. The following performance tests were performed on the Insulin syringe using a fixed needle:

- (i) ISO 7864:2016, Sterile hypodermic needles for single use — Requirements and test methods
- (ii) ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices—Requirements and test methods
- (iii) ISO 8537:2016, Sterile single-use syringes, with or without needle, for insulin

Biocompatibility

In accordance with ISO 10993-1, the needle is classified as: Externally Communicating Device, Blood Path Indirect, Prolonged Contact (<24hours). The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Acute systemic toxicity
- Pyrogenicity
- Hemocompatibility
- Subacute systemic toxicity

Sterilization, Shipping and shelf life

- (i) EO sterilization validation as per ISO11135-2014
- (ii) Pyrogen testing as per USP <85> Bacterial Endotoxin Test
- (iii) EO residual as per ISO 10997-7
- (iv) Stimulated shipping as per ASTM D4169
- (v) Sterile barrier Package testing performed on the proposed device (ISO 11138, IP)
- (vi) Seal strength EN 868-5
- (vii) Bubble test ASTM 2096
- (viii) Dye Penetration ASTM F1929-15

Shelf life: Shelf life of 5 years validated using FDA recognized ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

VIII. CONCLUSION

The difference between the predicate and subject device do not raise any new different questions of safety or effectiveness.

The SPM manufactured Insulin syringe is substantially equivalent to Insulin Syringe in K223453.

IX. Summary of Similarities & Difference of subject device with the predicate device and Justification:

The subject device shares equivalent indications for use, device operation, and overall technical and

functional capabilities to the predicate device. The difference in some materials of components, configuration, and sizes have been evaluated through non-clinical testing; the tests are in accordance with those established in the standards, ISO 7864-2016, ISO 9626:2016 & ISO 8537:2016. Therefore, the differences between the predicate device (K223453) and the subject device do not raise any new or different questions of safety or effectiveness. Performance testing data demonstrates that the proposed device is substantially equivalent to the predicate device with respect to the indications for use, target populations, and technological characteristics.