July 16, 2021
Lifelong Meditech Private Limited
Hamendra Srivastava
Director & CEO
Plot No.18, Sector-5, IMT Manesar
Gurugram, Haryana 122050
India

Re: K210103
Trade/Device Name: Lifelong Matrix/Lifelong Premium/Safeway syringe with/without needle
Regulation Number: 21 CFR 880.5860, 21 CFR 880.5570
Regulation Name: Piston Syringe, Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: June 10, 2021
Received: June 15, 2021

Dear Hamendra Srivastava:

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,

For Rumi Young
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210103

Device Name
Lifelong Matrix/Lifelong Premium/Safeway syringe with or without needle

Indications for Use *(Describe)*
Lifelong Matrix/Lifelong Premium/Safeway syringe with or without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

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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510(K) Summary- K210103

3.1 Submission Sponsor:

Lifelong Meditech Private Limited
Plot No.18, Sector-05, IMT, Manesar,
Gurugram, Haryana (INDIA)
Pin-122050.

3.2 Date:

July 14, 2021

3.3 Contact Person:

Hamendra Nath Srivastava,
Director and CEO
Tel: +91 9810661915;
Fax Number: +91 124-4406699
Email: hsrivastava@lifelongindia.com

3.4 Device Identification:

Trade/Proprietary Name: Lifelong Matrix/Lifelong Premium/Safeway syringe with/without needle

Common/Usual Name: Piston Syringe, Hypodermic Single Lumen Needle

Classification Panel: General Hospital

Classification Regulation:

- Piston Syringe- 21 CFR 880.5860.
- Hypodermic Single Lumen Needle- 21 CFR 880.5570

Device Code:

- FMF- Piston Syringe
- FMI - Hypodermic Single Lumen Needle

Device Class: Class II

3.5 Predicate Device:

K060211 - Wuzhou Syringe with/without needle

3.6 Device Description:

The Lifelong Matrix/Lifelong Premium/SAFEWAY syringe with or without needle is a standard piston syringe that consists of a calibrated hollow barrel and a movable plunger. The needle consists of needle tube, needle hub, needle cap. At one end of the barrel there is a male Luer Slip/Lock connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle or for attaching other devices with a female Luer. The syringe and needles are sterilized by ETO gas. It is a non-pyrogenic and single use device. The main raw materials for syringes are polypropylene and thermoplastic elastomer and for needles raw materials are polypropylene and stainless steel (SS-304).

The proposed device is available in a variety of combination of needle size and syringe volume. The syringe size, needle gauges is provided in following table.

Table No.-01

Syringe Size	Needle Gauge	Needle length	Wall type
1mL, 2mL, 3mL, 5mL, 10mL, 20mL	16G,	1", 1¼", 1½"	Thin Wall
	18G,	1", 1¼", 1½"	Thin Wall
	19G,	1", 1¼", 1½"	Thin Wall
	20G,	1", 1¼", 1½"	Thin Wall
	21G,	1", 1¼", 1½"	Thin Wall
	22G,	1", 1¼", 1½"	Thin Wall
	23G,	1", 1¼", 1½"	Thin Wall
	24G,	1", 1¼", 1½"	Thin Wall
	25G,	½", ¾", ⅝", 1", 1¼", 1½"	Thin Wall
	26G.	½", ¾", ⅝" 1", 1¼", 1½"	Regular Wall

3.7 Indication for Use:

Lifelong Matrix/Lifelong Premium/SAFEWAY syringe with or without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

Characteristics	**Subject Device** Lifelong Matrix/ Lifelong Premium/ Safeway syringe with/without needle K210103	**Predicate Device** Wuzhou Syringe with/without needle K060211
Indication for Use	Lifelong Matrix/ Lifelong Premium/ Safeway syringe with/without needle intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	The Wuzhou Syringe, with/without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

Prescription Only or Over the Counter	Prescription Only	Prescription Only

Discussions of differences in Indication for use statement:

The indication for use statement for the subject device is identical to the predicate device.

3.8 Technological Differences:

The Lifelong Matrix/Lifelong Premium/SAFEWAY syringe with or without needle has the following similarities with the predicate device - Wuzhou Syringe, with/without needle (K060211) which is a 510 (K) cleared device:

Technological Characteristics		**Subject Device K210103**	**Predicate Device (K060211)**	**Comparison**
Indications for Use		Lifelong Matrix/Lifelong Premium/Safeway syringe with or without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	The Wuzhou Syringe, with/without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	Same
Product Code		FMF, FMI	FMF, FMI	Same
Regulation Number		21 CFR 880.5860, 21 C.F.R. 880.5570	21 CFR 880.5860, 21 C.F.R. 880.5570	Same
Class		II	II	Same
Needle Gauge		16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, & 26G.	16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, & 26G.	Same
Size		1ml, 2ml, 3ml, 5ml,10ml & 20ml	1mL. 2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL and 100mL.	Similar, the predicate device includes additional models of 30mL, 60mL & 100mL, which do not raise any issue in safety and effectiveness of our device.
Needle length	16G to 24G	1", 1¼", 1½" (25mm to 40mm)	1", 1¼", 1½" (25mm to 40mm)	Same

510(K) Summary- K210103

Technological Characteristics		**Subject Device K210103**			**Predicate Device (K060211)**			**Comparison**
	25G & 26G	½", ¾", ⅝", 1", 1¼", 1½" (12mm to 40mm)			½", ¾", ⅝", 1", 1¼", 1½" (12mm to 40mm)			
Needle bevel		09º to 13º			09º to 13º			Same
Needle wall type	16G to 25G	Thin wall			Thin wall			Same
	26G	Regular wall			Regular wall			
Needle point (Sharpness test)		Needles point appear sharp, free from feather, edges, burrs and hooks. Needle point sharpness force & gliding force is with in limit			Needles point appear sharp, free from feather, edges, burrs and hooks. Needle point sharpness force & gliding force is with in limit			Same
Dose accuracy		Capacity less than half of nominal capacity (mL)			Capacity less than half of nominal capacity (mL)			Similar
		Size (mL)	Volume tested (mL)	Accuracy (mL)	Size (mL)	Volume tested (mL)	Accuracy (mL)	
		1mL	0.4	0.392-0.412	1mL	0.4	0.394-0.410	
		2mL	0.5	0.498-0.510	2mL	0.5	0.500-0.508	
		3mL	1.0	1.011-1.022	3mL	1.0	1.008-1.020	
		5mL	2.0	2.011-2.021	5mL	2.0	2.007-2.016	
		10mL	2.0	2.011-2.052	10 mL	2.0	2.012-2.042	
		20mL	5.0	5.038-5.082	20 mL	5.0	5.025-5.060	
		Capacity greater than half of nominal capacity (mL)			Capacity greater than half of nominal capacity (mL)			
		1mL	0.8	0.794-0.814	1mL	0.8	0.791-0.804	
		2mL	1.5	1.498-1.510	2mL	1.5	1.495-1.507	
		3mL	2.0	2.010-2.032	3mL	2.0	2.006-2.022	
		5mL	4.0	4.012-4.032	5mL	4.0	4.002-4.022	

510(K) Summary- K210103

Technological Characteristics	Subject Device K210103			Predicate Device (K060211)			Comparison
	10mL	8.0	8.012-8.052	10 mL	8.0	8.018-8.062	
	20mL	15.0	14.998-15.096	20 mL	15.0	15.098-15.167	
Inner diameter	Needle Gauge	Inner diameter		Needle Gauge	Inner diameter		Similar & meets the requirements of ISO 9626.
	16G	1.281 to 1.289mm		16G	1.279 to 1.288mm		
	18G	0.980 to 0.990mm		18G	0.981 to 0.989mm		
	19G	0.780 to 0.790mm		19G	0.779 to 0.787mm		
	20G	0.495 to 0.505mm		20G	0.492 to 0.500mm		
	21G	0.570 to 0.580mm		21G	0.569 to 0.575mm		
	22G	0.460 to 0.470mm		22G	0.461 to 0.469mm		
	23G	0.400 to 0.405mm		23G	0.401 to 0.405mm		
	24G	0.360 to 0.370mm		24G	0.359 to 0.371mm		
	25G	0.295 to 0.305mm		25G	0.292 to 0.303mm		
	26G	0.350 to 0.450mm		26G	0.351 to 0.452mm		
Residual volume (Dead Space)	Size of Syringe	Residual volume		Size of Syringe	Residual volume		Similar & meets the requirements of ISO7886-1.
	1mL	0.037 to 0.045mL		1mL	0.046 to 0.054mL		
	2mL	0.054 to 0.062mL		2mL	0.058 to 0.065mL		
	3mL	0.055 to 0.065mL		3mL	0.055 to 0.064mL		
	5mL	0.060 to 0.065mL		5mL	0.057 to 0.063mL		
	10mL	0.077 to 0.090mL		10mL	0.085 to 0.092mL		
	20mL	0.087 to 0.120mL		20mL	0.097 to 0.115mL		

510(K) Summary- K210103

Technological Characteristics	**Subject Device K210103**		**Predicate Device (K060211)**		**Comparison**
Needle cover removal force	15N to 25N		13N to 24N		Similar
Needle hub/needle bond strength	**Needle Gauge**	**Bond strength**	**Needle Gauge**	**Bond strength**	Similar & meets the requirements of ISO7864.
	16G	110 to 195N	16G	96 to 165 N	
	18G	95 to 115 N	18G	85 to 110 N	
	19G	80 to 134 N	19G	82 to 130 N	
	20G	78 to 118 N	20G	85 to 128 N	
	21G	70 to 140 N	21G	70 to 125 N	
	22G	84 to 140 N	22G	80 to 130 N	
	23G	70 to 135 N	23G	72 to 125 N	
	24G	65 to 110 N	24G	60 to 110 N	
	25G	55 to 90 N	25G	55 to 85 N	
	26G	50 to 85 N	26G	52 to 87 N	
Storage conditions.	Store in a cool and dry place		Store in cool and dry place		Same
Configuration	Plunger Barrel Gasket Needle Hub Needle Cover Needle Tube		Plunger Barrel Gasket Needle Hub Needle Cover Needle Tube		Same
Operation Mode	For manual use only		For manual use only		Same
Connector Type	Luer Slip and Luer Lock		Luer Slip and Luer Lock		Same
Sterility condition	EO Sterilized		EO Sterilized		Same
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards		Conforms to the requirement of ISO 10993 series Standards		Same
	No Cytotoxicity		No Cytotoxicity		Same
	No Irritation to Skin		No Irritation to Skin		Same
	No sensitization		No sensitization		Same
	No Hemolysis		No Hemolysis		Same
Performance safety & effectiveness	Complies with ISO 7886-1 ISO 7864 ISO 9626 ISO 80369		Complies with ISO 7886-1 ISO 7864 ISO 9626 ISO 594-1/-2		The predicate device complied to ISO 594-1/2. The ISO 594-1/2 is replaced with ISO 80369

Discussions of Differences in Technological characteristics:

The differences between the predicate and the subject device are as follows:

- The predicate device has additional models of syringes i.e. 30mL, 60mL & 100mL, which do not raise any new or different questions on safety or effectiveness of the subject devices.
- The conical fitting of predicate device complied with ISO 594-1/-2 and the conical fitting of subject device complies with the ISO 80369. The ISO 594-1/-2 has been updated and replaced with ISO 80369 in 2016, which does not raise any new or different questions of safety or effectiveness of the subject devices.

Hence, the device is considered as substantially equivalent to the predicate device.

3.9 Summary Performance Testing:

The device complies with the following standards:

A. **Hypodermic Needles:**

- 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 6009 Fourth edition: Hypodermic needles for single use – Color coding for Identification

B. Syringes:

- ISO 7886-1:2017 “Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
- ISO 80369-7:2016 “Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

Biocompatibility:

In accordance with ISO 10993-1 the syringe with needle is classified as external communicating device coming in contact with blood path indirect for contact period for less than 24hrs.

The Stainless-Steel part of Needle is considered as external communicating device coming in contact with circulating blood for contact period for less than 24 hours.

The biocompatibility tests were performed in accordance with the following standards:

- Cytotoxicity – ISO 10993-5:2009 (E) “Biological evaluation of medical devices – Part 5
- Intracutaneous Reactivity – ISO 10993-10:2010 (E) “Biological Evaluation of Medical Devices – Part 10
- Skin Sensitization – ISO 10993-10:2010 (E): “Biological Evaluation of Medical Devices – Part 10
- Acute Systemic Toxicity – ISO 10993-11:2006 (E): “Biological Evaluation of Medical Devices – Part 11
- Hemolysis – ISO 10993-4:2017 (E): “Biological Evaluation of Medical Devices – Part 4
- Bacterial Reverse Mutation (AMES) – ISO 10993-3:2014 “Biological evaluation of medical devices — Part 3
- Material-mediated Pyrogenicity – ISO 10993-11:2017(E): “Biological Evaluation of Medical Devices-Part-11
- Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria

Sterility, Shipping, and Shelf-life:

The device is sterilized by Ethylene oxide sterilization method, the sterilization process was validated as per ISO 11135-1: 2014 “Sterilization of health-care products — Ethylene oxide —Requirements for the development, validation and routine control of a sterilization process for medical devices.

The EO residual were tested which meets the requirements of ISO 10993-7: 2008 “Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals”.

The Bacterial endotoxin testing of subject devices was performed by “Gel-Clot Method” as per recommended guideline “United States Pharmacopeia” (USP).

Packaging integrity: Packaging validation tests were conducted in accordance with the following standard:

- ISO 11607-2:2019 "Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes".
- Transport validation tests were conducted in accordance with ASTM D4169-16 "Standard Practice for Performance Testing of Shipping Containers and Systems"

Sterile Barrier Packaging Testing performed on the proposed device: The packaging integrity of subject devices was performed as per the FDA recognized standard ASTM F 1929- 15 “Standard test method for detecting the sealing leak in porous medical packaging by dye penetration method”.

Shelf life: Shelf life of Lifelong Matrix/Lifelong Premium/Safeway syringe with or without needle is 5years. Validated using the FDA recognized standard ASTM F1980-16 “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”

Conclusion:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Lifelong Matrix/Lifelong Premium/Safeway syringe with or without needle, is substantially equivalent to the Wuzhou Syringe with/without needle with respect to the indications for use, target populations, treatment method, and technological characteristics.