July 18, 2023

Lifelong Meditech Private Limited
℅ Atonu Dutta
CEO
Alceon
Saarthi Complex, Nutan Bharat Society, Alkapuri
Vadodara, Gujarat 390007
India

Re: K222925
Trade/Device Name: Hypodermic Syringes & Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI, MEG
Dated: July 10, 2023
Received: July 14, 2023

Dear Atonu Dutta:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2023.07.18 15:07:10 -04'00'

For CAPT Alan Stevens
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)*
K222925

Device Name
Sterile Hypodermic Syringe With Needle or Without Needle for Single use, Sterile Hypodermic Safety Syringe (Clip Type) With Needle or Without Needle for Single use, Sterile Hypodermic Safety Syringe (Needle Retractable) With Needle for Single Use, Sterile Hypodermic Needle for Single Use

Indications for Use *(Describe)*

Sterile hypodermic single use syringe with needle or without needle:
The Sterile Hypodermic syringe with needle or without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

Sterile hypodermic safety syringe (clip type) for single use with needle or without needle:
The sterile hypodermic safety syringes for single use is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body. After injection, the anti-needle stick feature is manually activated to aid in the prevention of accidental needle stick injuries.

Sterile hypodermic safety syringes (needle retractable type) for single use with needle:
The needle retractable safety syringe is to be used for intra-muscular or subcutaneous injection of medications into a patient and is intended to prevent needle stick injuries. Needle retractable safety syringe is not intended to be used for withdrawing blood. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.

Sterile hypodermic needle for single use:
The Sterile Hypodermic needle 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

1. Submission Sponsor

Hamendra Nath Srivastava,
(Director and CEO)
Tel:+91 9810661915;
Email: hsrivastava@lifelongindia.com
LIFELONG MEDITECH PVT LTD
Plot No. 18, Sector – 5,
IMT Manesar, Gurgaon – 122050,
Haryana (INDIA),
Mfg. License No. MFG/MD/2019/000203

2. Primary Correspondent

Alceon Medtech Consulting
1008, 10th Floor, "OCEAN", Sarabhai Compound,
Near Centre Square mall, Dr. V.S. Marg, Vadodara,
Gujarat-390023, India.
Phone: (+91) 9925023428
Email: regulatory@alceonconsulting.com

3. Date of preparing the summary

19/06/2022

4. Device Details

Device name (Generic):	1. Sterile Hypodermic Syringe With Needle or Without Needle for Single use 2. Sterile Hypodermic Safety Syringe (Clip Type) With Needle or Without Needle for Single use 3. Sterile Hypodermic Safety Syringe (Needle Retractable Type) With Needle for Single use 4. Sterile Hypodermic Needle for Single use
Device name (Trade Name):	None
Classification Regulation:	21 CFR 880.5860, 21 C.F.R. 880.5570
Device Class:	Class II
Product Code:	FMF, FMI, MEG
Panel:	General hospital

5. Predicate Device

Predicate device for Hypodermic Syringes:

Subject Device Manufacturer	Subject Device	Primary Predicate Device 510K	Reference Device
Lifelong Meditech Pvt. Ltd.	1. Sterile hypodermic syringe with needle or without needle for single use	**K060211**	-
	2. Sterile hypodermic safety syringe (clip type) with needle or without needle for single use		**K163162**
	3. Sterile hypodermic safety syringe(Needle Retractable type) with needle or without needle for single use		**K051694**

Predicate device for Hypodermic Needle:

Subject Device Manufacturer	Subject Devices	Predicate Device
Lifelong Meditech Pvt. Ltd.	4. Sterile Hypodermic needle for single use	**K102584**

6. Device Description

The syringe consists of a plunger & gasket that's fits tightly within a cylindrical tube called a barrel. The plunger can be linearly pulled and pushed along the inside of the barrel, allowing the syringe to take-in and expel liquid or gas through a discharge nozzle at the front (open) end of the barrel. The open end of the syringe may be fitted with a hypodermic needle, a nozzle or tubing to help direct the flow into and out of the barrel. It has three different models of syringe along with needle as below:

1. Sterile Hypodermic Syringe with/ without needle for single use
2. Sterile Hypodermic Safety Syringe (Clip Type) with/ without needle for single use
3. Sterile Hypodermic Safety Syringe (Needle Retractable Type) with needle for single use
4. Sterile Hypodermic Needle for single use

In safety syringes a safety feature available, which is activated either manually or automatically. In clip type safety syringe, a clip is attached to the barrel and it is activated manually after use of syringe, which helps to prevent needle stick injury. In retractable type safety syringe a needle

retract after use of syringe, which helps to prevent needle stick injury. This feature is activated when plunger is pressed to expel the contents, the base of the plunger attached with the needle and pulling back of the plunger will cause the needle to retract in to the barrel of the syringe.

Tables 1,2 & 3 below gives information about the available lengths for each needle gauge and which syringe can use with what needles.

Proposed device:

The Hypodermic Syringes and Needle manufactured by Lifelong Meditech Pvt. Ltd. available with different sizes which described below.

Table 1: Sterile hypodermic syringe with needle or without needle for single use

Needle Size		**Colour**	**Length**	**Metric system (mm) / British System (in)**				
Metric (mm)	**British System**		13mm ½"	16mm 5/8"	19mm ¾"	25mm 1"	32mm 1 ¼"	38mm 1 ½"
0.45	26G	Brown						
0.50	25G	Orange						
0.55	24G	Purple						
0.60	23G	Deep Blue						
0.70	22G	Black						
0.80	21G	Deep Green						
0.90	20G	Yellow						
1.10	19G	Cream						
1.20	18G	Pink						
1.60	16G	White						
Syringe Sizes			30ml, 50ml and 60ml					

Table 2: Sterile hypodermic safety syringe (clip type) with needle or without needle for single use:

Needle Size		Colour	Length	Metric system (mm) / British System (in)				
Metric (mm)	British System		13mm ½"	16mm 5/8"	19mm ¾"	25mm 1"	32mm 1 ¼"	38mm 1 ½"
0.45	26G	Brown						
0.50	25G	Orange						
0.55	24G	Purple						
0.60	23G	Deep Blue						
0.70	22G	Black						
0.80	21G	Deep Green						
0.90	20G	Yellow						
1.10	19G	Cream						
1.20	18G	Pink						
1.60	16G	White						
Syringe Sizes			1ml, 2ml, 3ml, 5ml, 10ml and 20ml.					

Table 3: Sterile hypodermic safety syringes (needle retractable) with needle for single use:

Needle Size		Colour	Length	Metric system (mm) / British System (in)				
Metric (mm)	British System		13mm ½"	16mm 5/8"	19mm ¾"	25mm 1"	32mm 1 ¼"	38mm 1 ½"
0.45	26G	Brown						
0.50	25G	Orange						
0.55	24G	Purple						
0.60	23G	Deep Blue						
0.70	22G	Black						
0.80	21G	Deep Green						
0.90	20G	Yellow						
1.10	19G	Cream						
1.20	18G	Pink						
1.60	16G	White						
Syringe Sizes			2ml, 2.5ml, 3ml, 5ml, 10ml and 20ml					

Every gauge size needle available with every needle length and every needle can be used with every syringe.

The materials used in manufacturing of syringe & needle are have been found to be biocompatible following evaluation as outlined in Section 8 below. Table 1 below provides the information about raw material.

Table: 1 Raw Material

Components	Material	Grade
Barrel	Polypropylene	H200MK
Plunger	Polypropylene	H200MK
Gasket	Thermoplastic elastomer	8058, 8065 & SS 2165BKLL
Safety clip (Only for clip type model)	Polypropylene	H200MK
Molded Component Plunger	Polypropylene	(H110MA)
Scale Printing on barrel	Black ink	Not applicable
Dilution of black ink for scale printing on barrel	Thinner	Not applicable
Gasket Lubrication	Polydimethylsiloxane	DMC 1000cst
Barrel Lubrication	Polydimethylsiloxane	DMC 12500cst
Needle Hub	Polypropylene	H200MK
Needle cap	Polypropylene	H200MK
Needle tube	Stainless steel	304
Needle holder (only for needle retractable model)	Poly Oximethylene	HOSTAFORM C 9021
Adhesive/glue	Trimethylolpropanepolyglycidyl ether polymer	Not applicable
	Isobenzofurandione / diethylene tri - amine reaction products	Not applicable
	Bisphenol A diglycidyl ether	Not applicable
Needle tube lubrication	Polydimethylsiloxane	DMC 10000cst

Indications For Use:

1. **Sterile hypodermic syringe with needle or without needle for single use:**
   The sterile hypodermic syringe with needle or without needle is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body.

2. **Sterile hypodermic safety syringe (Clip Type) with needle or without needle for single use:**
   The sterile hypodermic safety syringes for single use is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body. After injection, the anti-needle stick feature is manually activated to aid in the prevention of accidental needle stick injuries.

3. **Sterile hypodermic safety syringes (Needle Retractable Type) with needle for single use:**
   The needle retractable safety syringe to be used for intra-muscular or subcutaneous injection of medications into a patient and is intended to prevent needle stick injuries. Needle Retractable Safety Syringe is not intended to be used for withdrawing blood. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.

4. **Sterile hypodermic needle for single use:**
   The sterile hypodermic needle intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

7. Comparison to a predicate device

7.1 Comparison to Predicate Device for Hypodermic Syringes

Description	Subject Devices (K222925)	Primary Predicate Device(K060211)	Comparison
Generic Name	1. Sterile Hypodermic Syringe With Needle or Without Needle for Single use 2. Sterile Hypodermic Safety Syringe (Clip Type) With Needle or Without Needle for Single use 3. Sterile Hypodermic Safety Syringe (Needle Retractable Type) With Needle for Single use	Sterile Piston Syringe	-

Manufacturer	Lifelong Meditech Pvt. Ltd.	Wenzhou Wuzhou Group Co., Ltd.	-
510 (K)	K222925	K060211	-
Class	II	II	-
Regulation Number	21 CFR 880.5860, 21 C.F.R. 880.5570	21 CFR 880.5860 21 C.F.R. 880.5570	-
Product Code	FMF, FMI, MEG	FMF, FMI	**Difference #1**
Indications for Use	**The Sterile Hypodermic syringe with needle 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.	**Difference #2**
	The Sterile Hypodermic Safety Syringe (Clip Type) With Needle or Without Needle for Single use is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body. After injection, the anti-needle stick feature is manually activated to aid in the prevention of accidental needle stick injuries.		
	The Sterile Hypodermic Safety Syringe (Needle Retractable Type) With Needle for Single use is to be used for intra-muscular or subcutaneous injection of medications		

		into a patient and is intended to prevent needle stick injuries. Needle Retractable Safety Syringe is not intended to be used for withdrawing blood. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.		
Configuration		Plunger Barrel Gasket Needle Hub Needle Cover Needle Tube Safety Clip Needle Holder	Plunger Barrel Gasket Needle Hub Needle Cover Needle Tube	**Difference #3**
Syringe Size		1, 2, 2.5, 3, 5, 10, 20, 30, 50, and 60 ml	1. 2, 3, 5, 10, 20, 30, 50, 60 and 100ml	**Difference #4**
Needle Gauge		16G,18G, 19G 20G, 21G, 22G, 23G, 24G, 25G, & 26G	16G, 18G, 19G 20G, 21G, 22G, 23G, 24G, 25G, & 26G	Same
Needle Length		½", ¾", ⅝", 1", 1¼", 1½"	½", ¾", ⅝", 1", 1¼", 1½"	Same
Needle wall type	**18G to 25G**	Thin wall	Thin wall	Same
		Regular wall	Regular wall	Same
	26G			
Operation Mode		For manual Single use only	For manual Single use only	Same
Connector Type		Luer Slip and Luer Lock	Luer Slip and Luer Lock	Same
Sterility condition		EO Sterilized	EO Sterilized	Same

7.2 Comparison to Predicate Device for Hypodermic Needle

Description	Subject Device	Predicate Device	Comparison

Generic Name	Sterile Hypodermic Needle for Single use	Hypodermic Needle	-
Manufacturer	Lifelong Meditech Pvt. Ltd.	International Medsurg Connection	-
Class	II	II	Same
Regulation Number	21 C.F.R. 880.5570	21 C.F.R. 880.5570	Same
Description	**Subject Device**	**Predicate Device**	**Comparison**
Product Code	FMI	FMI	Same
Clinical			
Intended Use	**The Sterile Hypodermic needle** intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.	This device is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.	Same
Technical Specification			
Configuration	Needle Hub Needle Cover/Cap Needle Tube	Needle Hub Needle Protector Cannula	Same
Needle Gauge	16G,18G, 19G 20G, 21G, 22G, 23G, 24G, 25G, & 26G	16G,17G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Similar, the predicate device include additional models of 27G,28G.29G, 30G
Needle length **16 G-26 G**	1/2”, 5/8”, 1”, 1.1/4”, 1.1/2”	1/2”, 5/8”, ¾”, 7/8", 1”, 1.1/4”, 1.1/2”	Similar, the predicate device include additional needle length of ¾”, 7/8"

Summary of Substantial equivalence

Difference #1:

The intended use of subject device is the same as the primary predicate. The subject device has three variations in which two variations have additional safety feature indications. The safety feature does not impact the devices' intended use and further mitigates the risk of accidental needle sticks. Hence, the difference does not raise new or different questions of safety and effectiveness as compared to the predicate.

Difference #2:

The intended use of subject devices is the same as the primary predicate. Moreover, the subject device has three variations in which two variations (Clip type & Needle Retractable Type) have additional safety feature indications. The addition of the safety feature is a technological characteristic that is intended to further mitigate the risk of accidental needle stick injuries, which is not a new or different question of safety and effectiveness.

Difference #3:

The intended use of the subject devices is the same as primary predicate but due to additional safety features in subjected device variants the configuration have some additional component (Safety clip, Needle Holder). The addition of the safety feature is a technological characteristic that is intended to further mitigate the risk of accidental needle stick injuries, which is not a new or different question of safety and effectiveness. The variants of hypodermic syringes are manufactured from same raw material as predicate and are all within the scope and the size of the cleared predicate. The subject devices were tested in accordance with ISO7886-1:2017, ISO 7886-4: 2018, ISO 80369-7:2016 and ISO 23908:2011 standards.

Difference #4:

The intended use of the different sizes are the same as the predicate device. The difference in sizes are made of the same raw materials and the same manufacturing process. The differences in size does not raise new or different questions of safety and effectiveness. Additionally, the proposed sizes are within the cleared range of the predicate. All syringes are designed and tested in accordance with ISO 7886-1:2017, ISO 7886-4: 2018 and ISO 80369-7:2016 standards. Considering these factors, sizes of syringes do not add any additional safety issues and would perform as intended.

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
ISO7886-1:2017	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
ISO 7864:2016	Sterile hypodermic needles for single use — Requirements and test methods
ISO7886-4:2018	Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature
ISO 80369-7: 2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
ISO 23908:2011	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 6009:2016	Hypodermic needles for single use — Colour coding for identification
USP <71>	Sterility
IP-2022 & USP <85>	Bacterial Endotoxin test
USP <788>	Particulate Contamination
Bio Compatibility Test:	
ISO 10993-5: 2009 - In-vitro Cytotoxicity ISO 10993-10:2010 - Skin sensitization ISO 10993-10:2010 - Intracutaneous reactivity ISO10993-4, 2002/Amd 1:2006 – Hemocompatibility ISO 10993-11:2017 (E) USP 43 <151> - Material mediated pyrogenicity ISO 10993-11:2017- Acute systematic toxicity	
Packaging & Transit 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:
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 & BET:
ISO 10993-7:2008/Amd1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants
The Bacterial endotoxin testing of subject devices was performed by the “Gel-Clot Method” and meets the requirement of IP-2022 & 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 devices are determined to be Substantially Equivalent (SE) to the predicate devices.