W. L. Med Co., Ltd.
℅ Peter Chung
President
Plus Global
300, Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K210748
Trade/Device Name: Well-life™ Pen Needles, Well-life™ Safety Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 25, 2022
Received: April 27, 2022

Dear Peter Chung:

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 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)*
K210748

Device Name
Well-life™ Safety Pen Needles
Well-life™ Pen Needles

Indications for Use *(Describe)*
This device is intended for use with pen injector devices for the subcutaneous injection of insulin.

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
K210748

1. Applicant

1) Company : W. L. MED Co., Ltd.
2) Address : 246, Geumgwangosan-ro, Geumgwang-yeon, Anseong-si, Gyeonggi-do, Korea
3) Tel : 82-31-8057-2162
4) Fax : 82-31-8057-2163
5) Prepared date : Feb 26, 2021
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : May. 20, 2022

2. Device Information

1) Trade name : Well-life™ Safety Pen Needles and Well-life™ Pen Needles
2) Common name : Hypodermic single lumen needle
3) Regulation name : Needle, hypodermic, Single Lumen
4) Product code : FMI
5) Regulation number : 880.5570
6) Class of device : Class II
7) Panel : General Hospital
8) Model Types

G-type

G2904	G2905	G2906	G2908	G2910	G2912	G3004	G3005
G3006	G3008	G3010	G3012	G3104	G3105	G3106	G3108
G3110	G3112	G3204	G3205	G3206	G3208	G3210	G3304
G3305	G3306	G3308	G3310	G3404	G3405	G3406	G3408

P-type

P2904	P2905	P2906	P2908	P2910	P2912	P3004	P3005
P3006	P3008	P3010	P3012	P3104	P3105	P3106	P3108
P3110	P3112	P3204	P3205	P3206	P3208	P3210	P3304
P3305	P3306	P3308	P3310	P3404	P3405	P3406	P3408

S-type

S2904	S2905	S2906	S2908	S2910	S2912	S3004	S3005
S3006	S3008	S3010	S3012	S3104	S3105	S3106	S3108
S3110	S3112	S3204	S3205	S3206	S3208	S3210	S3304
S3305	S3306	S3308	S3310	S3404	S3405	S3406	S3408

3. The legally marketed device to which we are claiming equivalence

Predicate Device #1: K113186, ShinaPen / SHINA CORPORATION
Predicate Device #2: K172095, Autokeeper / MedExel Co., Ltd.

4. Device description

The Well-life™ Safety Pen Needles and Well-life™ Pen Needles are single use, sterile, disposable medical devices intended to be used with compatible insulin pen injectors. The pen needles are intended for use by adults and pediatrics in a home, clinical, or hospital environment. The devices are sterilized by Ethylene Oxide (EO) to a sterility assurance level of 10^{-6}.

The Well-life™ Pen Needles consist of a Needle, Hub, Needle Cap, and Sterile Cap. The Well-life™ Safety Pen Needles consist of a Needle, Hub, Needle Cap, Sterile Cap, Guide, Safety Cap, and Spring. To use the devices, the Needle Hub is screwed onto a compatible pen injector.

The Well-life™ Safety Pen Needle (i.e., S type) is designed to reduce occurrence of accidental needle sticks from patient end of the needle by providing a shield that covers and locks the needle after use. As the user proceeds

with inserting the needle into the skin, the Needle Cap will retract. After the injection is completed and needle is removed from the skin, the safety cap will automatically extend to cover the needle. Once the pen needle is locked out, it can no longer be used.

Model	Gauge	Length	Wall Type	Model	Gauge	Length	Wall Type
G2904	29G	4	RW	***P2904***	29G	4	RW
G2905		5		***P2905***		5	
G2906		6		***P2906***		6	
G2908		8		***P2908***		8	
G2910		10		***P2910***		10	
G2912		12.7		***P2912***		12.7	
G3004	30G	4	TW	***P3004***	30G	4	TW
G3005		5		***P3005***		5	
G3006		6		***P3006***		6	
G3008		8		***P3008***		8	
G3010		10		***P3010***		10	
G3012		12.7		***P3012***		12.7	
G3104	31G	4		***P3104***	31G	4	
G3105		5		***P3105***		5	
G3106		6		***P3106***		6	
G3108		8		***P3108***		8	
G3110		10		***P3110***		10	
G3112		12.7		***P3112***		12.7	
G3204	32G	4		***P3204***	32G	4	
G3205		5		***P3205***		5	
G3206		6		***P3206***		6	
G3208		8		***P3208***		8	
G3210		10		***P3210***		10	
G3304	33G	4		***P3304***	33G	4	
G3305		5		***P3305***		5	
G3306		6		***P3306***		6	
G3308		8		***P3308***		8	
G3310		10		***P3310***		10	
G3404	34G	4		***P3404***	34G	4	
G3405		5		***P3405***		5	
G3406		6		***P3406***		6	
G3408		8		***P3408***		8	
S2904	29G	4	RW	***S3110***	31G	10	TW
S2905		5		***S3112***		12.7	
S2906		6		***S3204***	32G	4	
S2908		8		***S3205***		5	
S2910		10		***S3206***		6	
S2912		12.7		***S3208***		8	
S3004	30G	4	TW	***S3210***		10	

S3005		5		***S3304***		4	
S3006		6		***S3305***		5	
S3008		8		***S3306***	33G	6	
S3010		10		***S3308***		8	
S3012		12.7		***S3310***		10	
S3104		4		***S3404***		4	
S3105	31G	5		***S3405***	34G	5	
S3106		6		***S3406***		6	
S3108		8		***S3408***		8	

5. Intended Use

This device is intended for use with pen injector devices for the subcutaneous injection of insulin.

6. Performance data:

1) Bench testing was performed for the Well-life™ Safety Pen Needle and Well-life™ Pen Needle. The tests, shown below, demonstrated that the device performs in a substantially equivalent manner to the predicate device.

Test item	**Requirements**
Dimension	ISO 11608-2:2012 Dimension, General, Dimension for needles
Flow rate	ISO 11608-2:2012 Determination of flow rate through the needle
Bond between hub and needle tube	ISO 11608-2:2012 Bond between hub and needle tube
Needle point freedom from defects lubrication test	ISO 11608-2:2012 Needle point, Freedom from defects, Lubrication
Dislocation of measuring point at patient end	ISO 11608-2:2012 Dislocation of measuring point at patient end
Compatibility of needles and injector system	ISO 11608-2:2012 Determination of functional compatibility with needle-based injection systems
Ease of assembly and disassembly	ISO 11608-2:2012 Ease of assembly and disassembly
Materials	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Surface finish and visual appearance	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Cleanliness	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Limits for acidity and alkalinity	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Size Designation	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Dimension	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Stiffness	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Resistance to breakage	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Resistance to corrosion	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.
Simulated Clinical Use test	Referenced with ISO23908:2011
Elasticity	MFDS Notification No 2020-20 “Needle, aspiration/injection, single-use”
Flexural rigidity test	MFDS Notification No 2020-20 “Needle, aspiration/injection, single-use”
Draw test	Over 11N
Safety device operation test	The Safety cap should work after injection
Extraction test	MFDS Notification No 2020-20 “Needle, aspiration/injection, single-use”
Sterility	Korean Pharmacopeia / General Requirements for tests and assays / Sterility test
EO gas residuals	ISO 10993-7:2008 Ethylene oxide sterilization residuals

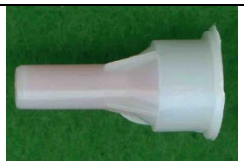
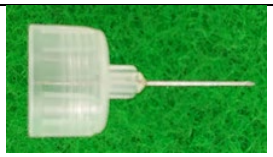
2) Biocompatibility

#	Test item	Test method / Test criteria
1	Cytotoxicity	ISO 10993-5(2009) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2	Acute systemic toxicity test	ISO 10993-11(2009) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
3	Pyrogen test	ISO 10993-11 Test for systemic toxicity, pyrogen test
4	Sensitization test	ISO 10993-10 (2010)

5	Hemolytic test	ISO 10993-4:2017, ASTM F756-17
6	Intracutaneous reactivity test	ISO 10993-10 (2010)
7	Endotoxin test	ISO 10993-11 Tests for systemic toxicity

The performance tests demonstrated that the subject device performs in a substantially equivalent manner to the predicate device.

7. Predicate device comparison table
Well-life™ Pen Needle

Device Name		**Subject Device**	**Predicate Device #1**	**Remark**
Manufacturer		W.L. MED	SHINA CORPORATION	N/A
510(k) Number		N/A	K113186	N/A
Product Code		FMI	FMI	Same
Design	Sterile Cap			Similar
	Needle Cap			Similar
	Needle And Hub			Similar
Intended Use		The Well-life pen needle is designed for use with a pen injector for the subcutaneous injection of insulin.	The ShinaPen® is designed for use with a pen injector for the subcutaneous injection of insulin.	Similar
Length		4mm, 5mm, 6mm, 8mm, 10 mm , 12.7mm	4mm, 6mm, 8mm, 12.7mm	Different
Gauge		29G 30G 31G 32G, 33G, 34G	29G 30G 31G 32G	Different
Biocompatibility		Conform ISO 10993-1	Conform ISO 10993-1	Same
Materials	Needle	STS304	STS304	Same
	Hub	1-Propene polymer with ethene	Polypropylene	Same
	Needle cap	Polypropylene	Polyethylene	Different
	Silicon	Poly di-methyl siloxane	Poly di-methyl siloxane	Same
Sterility		Sterilized by ethylene oxide gas SAL = 10^{-6}	Sterilized by ethylene oxide gas SAL = 10^{-6}	Same

Type of use	Single use, Disposable	Single use, Disposable	Same

The subject device and predicate device outlined above consist of the same materials for each component. The difference in needle length does not impact substantial equivalence as the subject devices needle lengths are in range of the predicate. The difference in needle gauge does not impact substantial equivalence based on the performed bench testing. The difference in Hub material does not impact substantial equivalence based on performed biocompatibility testing.

Well-life™ Safety Pen Needle

Device Name		Subject Device	Predicate Device #2	Remark
Manufacturer		W.L. MED	MedExel	N/A
510(k) Number		N/A	K172095	N/A
Product Code		FMI	FMI	Same
Design	Primary container			Similar
Intended Use		The Well-life safety pen needle is designed for use with a pen injector for the subcutaneous injection of insulin.	The MedExel Autokeeper is intended for use with insulin pens for the subcutaneous injection of insulin. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks form the patient end of the needle. The shield also serves to hide the needle before and after injection.	Similar
Length		4mm, 5mm, 6mm, 8mm, 10 mm , 12.7mm	4mm, 5mm, 6mm, 8mm	Same
Gauge		29G 30G 31G 32G, 33G, 34G	29G, 30G, 31G, 32G, 33G, 34G	Similar
Biocompatibility		Conform ISO 10993-1	Conform ISO 10993-1	Same
Materials	Needle tube	STS304	STS304	Same
	Hub	1-Propene polymer with ethene	Polypropylene	Different
	Primary container	Polyethylene	Polyethylene	Same
	Silicon	Poly di-methyl siloxane	Poly di-methyl siloxane	Same
Sterility		Sterilized by ethylene oxide gas SAL = 10^{-6}	Sterilized by ethylene oxide gas SAL = 10^{-6}	Same

The subject device and predicate device outlined above consist of the same materials for each component. The difference in needle length does not impact substantial equivalence as the subject devices needle lengths are in range of the predicate. The difference in needle gauge does not impact substantial equivalence based on the performed bench testing. The difference in Hub material does not impact substantial equivalence based on performed biocompatibility testing.

8. Conclusion

Comparison results demonstrate that the specifications and performance of the device are substantially equivalent to the legally marketed predicate devices. Therefore, it is concluded that Well-life™ Pen Needles and Well-life™ Safety Pen Needles are substantially equivalent to the legally marketed predicate devices.