November 4, 2022

Medwell Technology Ltd
Jonathan Gilbert
Regulatory/Clinical Affairs Consultant to Medwell Technology Ltd
1641 Jeurissen Lane
Chanhassen, Minnesota 55317

Re: K212764
Trade/Device Name: Medwell Technology Polycarbonate Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: October 11, 2022
Received: October 12, 2022

Dear Jonathan Gilbert:

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,

Alan M. Stevens -S3

CAPT Alan M. 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)*
K212764

Device Name

Medwell Technology Polycarbonate Syringes

Indications for Use *(Describe)*

The Medwell Technology Polycarbonate Syringes are intended 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.

K212764 510(k) Summary

1. Sponsor:	Medwell Technology Ltd 8th Building, Pujing, Fumin Industry Zone, DaLang Town Dongguan City, Guandong 523770 China
Contact	Jon Gilbert, Consultant 906.361.3237 jgilb.raca@gmail.com
2. Preparation Date:	November 1, 2022
3. Subject Device **Common Name:** **Trade Name:** **Regulation Number:** **Regulation Name:** **Classification Panel:** **Regulatory Class:** **Product Code:**	 Piston Syringes Medwell Technology Polycarbonate Syringes 21 CFR 880.5860 Piston syringe General Hospital Class II FMF
4. Predicate Device	MHC Standard and NRFit Tip Syringes K171131, cleared November 8, 2017
5. Device Description:	The Medwell Technology PC Syringes are provided sterile or in bulk non-sterile for further processing (e.g. sterilization). They are single use devices consisting of rigid polycarbonate barrels with luer slip or luer lock tips and various colored plungers with a synthetic rubber tip (stopper). The syringe barrels are printed with graduated markings in cc (1- 30 milliliters) indicating the volume of liquid inside the various size syringe barrels.
6. Indication for Use:	The Medwell Technology Polycarbonate Syringes are intended to inject fluids into or withdraw fluids from the body.

7. Substantially Equivalent (SE) Comparison:

Table 2. Technological Characteristics & Substantial Equivalence Table

Item	Propose Device K212764	Predicate Device K171131	Comparison*
Product name	Sterile and Non-sterile Hypodermic Syringes for Single Use	Sterile and Non-sterile Hypodermic Syringes for Single Use	Same
Product Code	FMF	FMF	Same
Regulation No. Class	21 CFR 880.5860	21 CFR 880.5860	Same
Class	CLASS II	CLASS II	Same
Syringe Volume	1cc – 30cc	1cc – 30cc	Same
Nozzle Type	Luer slip; Luer lock	Luer slip; Luer lock	Same
Configuration and material	Barrel: Polycarbonate Plunger: ABS polymer Plunger Tip: Elastomer Silicone Oil: Medical Grade	Barrel: Polycarbonate Plunger: ABS Polymer Plunger Tip: Elastomer Silicone Oil: Medical Grade	Same
Operation Mode	Manual Use	Manual Use	Same
Syringe Performance	Complies with ISO 7886-1:2017	Complies with ISO 7886-1:2017	Same
Biocompatibility	Complies with ISO 10993 series standards for patient contact profile > 24 hrs ≤ 30 days	Complies with ISO 10993 series standards for patient contact profile > 24 hrs ≤ 30 days	Same
Rx Use / OTC Use	Yes / No	Yes / No	Same
Single Use	Yes	Yes	Same
Shelf-life	3 years	1 year	Same**
Sterilization	EO	EO	Same
SAL	10-6	10-6	Same
Label/Labeling	Complies with 21 CFR 801	Complies with 21 CFR 801	Same

*Subject device PC syringe components are comprised of same materials and manufactured using same manufacturing methods. K171131 references identical materials and manufacturing methods for standard PC syringes (NRFIT tip configurations excluded).

**Predicate device was cleared with performance testing supported by 1 year shelf life. 3 year shelf life assigned for subject device is consistent with performance data testing (accelerated aging, device performance and packaging verification) and raises no new questions about safety or performance.

The clinical technique, indications for use, technical specifications, materials used, sterility status (validation and sterility assurance level) as well as the biocompatibility status are identical between the subject and predicate syringes.

8. Non-Clinical Performance Testing:

The performance of the subject Medwell Technology PC Syringes is identical to the predicate devices as no material, manufacturing or technological changes have occurred.

Testing per ISO 7886-1, ISO 80369-7, and ISO 10993-1 were conducted to demonstrate conformance to the recognized standards and substantial equivalence with the predicate device.

Biocompatibility Testing:

In accordance with ISO 10993-1, the syringe complies with the standards for patient contact profile > 24 hrs $\leq$ 30 days.

Sterile Barrier Packaging Test

Sterile barrier packaging testing was performed on the proposed device, which include visual inspection (ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15) and dye penetration test (ASTM F1929-15). The test result showed that the device package can maintain its integrity.

Sterilization and Shelf-Life Test

The EO sterilization method has been validated per ISO 11135 and defines the routine control and monitoring parameters. The shelf life of the Sterile Hypodermic Syringe for Single Use is 3 years, determined based on stability studies which includes accelerated aging. Sterilization and shelf-life testing listed were performed on the proposed device.

Animal and Clinical Tests

Neither animal nor clinical testing was required to demonstrate performance of the subject and predicate devices. Product functionality has been adequately assessed by non-clinical tests.

9. Conclusion:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Medwell Technology PC Syringes are substantially equivalent to the Standard Syringes of K171131 with respect to the indications for use, target populations, treatment method, and technological characteristics.