January 24, 2022

Shandong Qinkai Medical Industry Co., Ltd.
Alice Gong
Manager
South Section of Quancheng Road, Medical Equipment
Industrial Park, Chengwu County
Heze City, Shandong Province 274200
China

Re: K211482
Trade/Device Name: Disposable Syringe with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: December 14, 2021
Received: December 27, 2021

Dear Alice Gong:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211482

Device Name
Disposable Syringe with Needle

Indications for Use *(Describe)*
Sterile single-use syringe with needle is 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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K211482 510(K) SUMMARY

Preparation Date:	January 24, 2022
Submitter Name:	Shandong Qinkai Medical Industry Co., Ltd., South Section of Quancheng Road, Medical Equipment Industrial Park, Chengwu County, Heze City, Shandong Province, China 274200
Contact Person:	Mr. Ou Kai Jiang General Manager
Telephone Number:	(86) 0530-6112108
Fax Number:	(86) 0530-6112108
E-mail Address:	490566042@qq.com
Trade Name:	Disposable Syringe with Needle
Regulation Name:	Syringe, Piston
Regulation Number:	21 CFR 880.5860
Product Code:	FMF
Device Class:	Class II
Regulation Name:	Hypodermic Single Lumen Needle
Regulation Number:	21 CFR 880.5570
Product Code:	FMI
Device Class:	Class II
Predicate Device:	K163161 Sterile Single-use Syringe with Needle

Device Description

The subject device is for single use only, which is comprised of syringes and needles with various specifications. The syringe consists of barrel, plunger, piston, and the needle consist of needle tube, needle hub, needle cap. The proposed devices shall be operated manually, and are not intended for use with syringe pumps. The proposed devices are available in a variety combination of needle size and syringe volume. The syringe sizes, needle gauges and lengths are provided in the following table.

Syringe Size	Needle Gauge	Needle Length
Available in 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml	Available in 18G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G	Available in 1/2", 5/8", 1", 1 1/4", 1 1/2"

The subject device is provided sterile and is for single use only. The EO gas sterilization process is validated with a resulting sterility assurance level (SAL) of 10^{-6}. It meets requirements of ISO 11135, sterilization of

health-care products for ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices.

Below is the list of different combinations:

No.	Syringe Size	Needle Gauge & Length
1	1 ml	30G*1/2", 29G*1/2", 28G*5/8"
2	2 ml	27G*1/2", 26G*1/2", 25G*1"
3	3 ml	25G*1", 23G*1 1/4", 22G*1 1/4"
4	5 ml	23G*1 1/4", 22G*1 1/2", 21G*1 1/2"
5	10 ml	22G*1 1/2", 21G*1 1/2", 20G*1 1/2"
6	20 ml	22G*1 1/2", 21G*1 1/2", 20G*1 1/2", 18G*1 1/2"
7	30 ml	21G*1 1/2", 20G*1 1/2", 18G*1 1/2"
8	50 ml	21G*1 1/2", 20G*1 1/2", 18G*1 1/2"

Indications for Use

Characteristic	**Predicate Device** Sterile Single-use Syringe with Needle K163161	**Subject Device** Disposable Syringe with Needle K211482
Indications for Use	Sterile Single-use Syringe with Needle is intended to inject fluids into or withdraw fluids from the body.	Sterile single-use syringe with needle is intended to inject fluids into or withdraw fluids from the body.
Prescription Only or Over the Counter	Prescription Only	Prescription Only

Discussions of differences in Indications for Use statement
The indications for use statement for the subject device is identical to the predicate device.

Technological Characteristics
The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Technological Characteristic	**Predicate Device** Sterile Single-use Syringe with Needle K163161	**Subject Device** Disposable Syringe with Needle K211482	**Comments**
Product Code	FMF and FMI	FMF and FMI	Same
Regulation Number	21 CFR 880.5860, 21 CFR 880.5570	21 CFR 880.5860, 21 CFR 880.5570	Same
Class	II	II	Same

Configuration and material	Barrel, Plunger, Needle hub and Needle cap is made of Polypropylene (PP). Piston is made of Polyisoprene. Needle tube is made of Stainless Steel, SUS304	Barrel, Plunger, Needle hub and Needle cap is made of Polypropylene (PP). Piston is made of Polyisoprene. Needle tube is made of Stainless Steel, SUS304	Same
Operation Mode	For manual use only	For manual use only	Same
Syringe Volume	1ml, 3ml, 5ml, 10ml, 20ml, 60ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml	Similar Comment 1
Connector Type	Luer Slip and Luer Lock	Luer Slip and Luer Lock	Same
Needle Gauge	18G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G	18G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G	Same
Needle Length	1/2", 5/8", 1", 1 1/4", 1 1/2"	1/2", 5/8", 1", 1 1/4", 1 1/2"	Same
Biocompatibility	meet ISO 10993 requirements.	meet ISO 10993 requirements.	Same
Sterilization	EO Sterilization	EO Sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Single Use	Single Use	Single Use	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Discussions of differences in technological characteristics

Comment 1

The subject device has more syringe volume specification than the predicated device, however the subject device has met the requirements of product performance standards and biocompatibility standards. The volume specifications are also within the overall range included in the predicate. This difference does not affect intended use, so it will not raise new questions of safety or effectiveness.

Performance Testing

Bench tests were conducted to verify that proposed device meet all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that proposed device complies with the following standards:

A. Physical, Mechanical and Chemical Tests performed on the proposed device:

Test Item	Standard
Syringe	ISO 7886-1: 2017 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
Needle	ISO 9626: 2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
Needle	ISO 7864: 2016 Sterile hypodermic needles for single use - Requirements and test methods
Luer connector	ISO 80369-7: 2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

B. Sterile Barrier Packaging Testing performed on the proposed device:

Test Item	Standard
Seal strength	ASTM F88/F88M-2015
Detecting seal leaks	ASTM F1929-2015
Determining integrity of seals	ASTM F1886/F1886M-2016

C. Sterilization and Shelf Life Testing performed on the proposed device:

Test Item	Standard
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 36-NF 31<85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package and Sterility Tests were performed on aging samples to verify the shelf life of 3 years for the subject device

D. The hub is made of pigmented material and the hub color for different needle gauge comply with ISO 6009:2016.

E. Biocompatibility Testing is conducted according to ISO 10993-1:2018:

Test Item	Standard
Cytotoxicity Test	ISO 10993-5:2009
Skin Sensitization Test	ISO 10993-10:2010
Intracutaneous Reactivity Test	ISO 10993-10:2010
Acute Systemic Toxicity Test	ISO 10993-11:2017
Pyrogen Test	ISO 10993-11:2017
Hemolysis Test	ISO 10993-4:2017
Particulate	USP <788>

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject Device, Disposable Syringe with Needle, K211482 is substantially equivalent to the predicate Device, Sterile Single-use Syringe with Needle, K163161.