Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
℅ Evan Hu
Marketing & Technical Manager
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, Shanghai 201114
China

Re: K220083
Trade/Device Name: LDV(Low Dead Volume)Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ, QNS
Dated: April 16, 2022
Received: April 25, 2022

Dear Evan Hu:

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)*

K220083

Device Name
LDV (Low Dead Volume) Syringe

Indications for Use *(Describe)*
The LDV (Low Dead Volume) Syringe is intended to be used for medical purpose to inject fluid into or withdraw fluid from 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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K220083 510(k) SUMMARY

1. **Preparation Date**
   5/25/2022

2. **Submitter**

   Manufacturer: Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
   Address: No.2 Guanyin Road, Taihu Economic Development Zone, Anqing City, Anhui Province, 246400, China
   Contact person: Bingyi Xiang, +86-556 5129666, hwj1@hongyu-wuzhou.cn
   Submission correspondent: Evan Hu, 86-18616124827, Evan.hu@mind-link.net

3. **Device**

   Trading name: LDV (Low Dead Volume) Syringe
   Common name: Sterile low dead space piston syringe with fixed hypodermic needle
   Classification name: Low Dead Space Piston Syringe
   Classification: Class II
   Product code: QNQ, QNS

4. **Predicate device**

   Primary predicate device: PLPT LDV (Low Dead Volume) Sterile Syringe – K210443
   Secondary predicate device: EZ-Injec LDV Sterile Safety Needle – K210444

5. **Indications for Use**

   The LDV (Low Dead Volume) Syringe is intended to be used for medical purpose to injectfluid into or withdraw fluid from body.

6. **Device description**

   The LDV (Low Dead Volume) Syringe is consistent with the calibrated syringe and permanent needle intended to be used for injection or withdrawal of fluids to or from the human body. The needle is fixed that cannot be removed. The needle cap is colored to differentiate the different types of needle models. The syringe plunger is well-designed to reduce the fluid waste, called low dead volume or low dead space.

The LDV (Low Dead Volume) Syringe has various colors, syringe volumes, needle gauge sizes, and needle length sizes, which could be applied in different clinic-use scenarios. Meanwhile, the device is sterilized with ethylene oxide and without any pyrogen. Therefore, this is a single-use device that should be immediately discarded after use.

Table. 1. Device specifications

Gauge	Needle Bevel	Needle Wall type	Needle length (inch)	Needle cap color	Syringe volume	Syringe type
31G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8,	White	0.3mL, 0.5mL, 1mL	Type 1, Type 2
		TW				
		ETW				
		UTW				
30G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8,	Yellow		
		TW				
		ETW				
		UTW				
29G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8,	Red		
		TW				
		ETW				
		UTW				
28G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1	Aquamarine blue		
		TW				
27G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1, 1 1/2,	Medium gray		
		TW				
26G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1,	Brown		
		TW				
25G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1, 1 1/2,	Orange		
		TW				
24G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1, 1 1/4,	Medium purple		
		TW				
23G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1, 1 1/8, 1 3/16, 1 1/4, 1 1/2,	Deep blue		
		TW				
		ETW				
22G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1, 1 3/16, 1 1/4, 1 1/2,	Black		
		TW				
		ETW				
21G	LB SB	RW	1/4, 5/16, 3/8, 1/2, 5/8, 3/4, 1, 1 1/4, 1 1/2	Deep blue		
		TW				
		ETW				
		UTW				

7. Indications for use/Intended use

The LDV (Low Dead Volume) Syringe is intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

8. Comparison of technological characteristics between proposed and predicate devices

Table 2. Characteristics comparison

Technological Characteristics	Proposed device LDV (Low Dead Volume) Syringe K220083	Primary predicate PLPT LDV (Low Dead Volume) Sterile Syringe K210443	Secondary predicate EZ-Injec LDV Sterile Safety Needle K210444	Remark
Indications for Use	The LDV (Low Dead Volume) Syringe is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	PLPT LDV (Low Dead Volume) Sterile Syringe is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	This product is intended for use to inject fluid into or withdraw fluids from parts of the body below the surface of the skin.	#1
Product code	QNQ, QNS	QNQ	QNS	#2
Regulation No.	21CFR 880.5860, 21 CFR 880.5570	21CFR 880.5860	21 CFR 880.5570	#3
Class	II	II	II	Same
Configuration and Material	(1) Needle cap (PE) (2) Needle (SUS 304) (3) Plunger stopper (Polyisoprene rubber) (4) Plunger (PP) (5) Barrel (PP)	(1) Barrel: PP (2) Plunger rod: PP (3) Plunger: Rubber	(1) needle cap/protector (PP) (2) needle (Stainless Steel 304) (3) needle hub (PP)	#4
Syringe volume	0.3mL, 0.5mL, 1mL	1mL	-	#5
Needle gauge and length	21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G 1/4”, 5/16”, 3/8”, 1/2”, 5/8”, 3/4”, 1”, 1 1/8”, 1 3/16”, 1 1/4”, 1 1/2” (6mm, 8mm, 10mm, 13mm, 16mm, 19mm,	-	25G 25mm	#6

	25mm, 28mm, 30mm, 32mm, 38mm)			
Need wall type and bevel	RW, TW, ETW, UTW LB, SB	-	TW Beveled	#7
Sharps prevention function	No safety guard	-	Safety guard	#8
Needle performance	Meet ISO 9226 and ISO 7864	-	Meet ISO 9226 and ISO 7864	Same
Syringe performance	Meet ISO 7886-1	Meet ISO 7886-1	-	Same
Dead space specification	0.3mL: ≤0.0025g(mL) 0.5mL: ≤0.0035g(mL) 1mL: ≤0.0039g(mL) Meet ISO 7886-1 clause 8 table 1	1mL: ≤0.023mL with 95% confidence/95% reliability Meet ISO 7886-1 clause 8 table 1	25G-25mm: ≤0.0054ml Meet ISO 7886-1 clause 8 table 1	#9
Sterility method	EO Sterilized	EO Sterilized	EO Sterilized	Same
Biocompatibility	Meet ISO 10993	Meet ISO 10993	Meet ISO 10993	Same

Notes:

#1: Intended use/Indications for use

The operation principle of the proposed device, the primary predicate device, and the secondary predicate device are precisely the same. The differences are the detailed description which does not affect the substantially equivalent of safety and effectiveness.

#2: Product code

The proposed device is a combination of a low dead volume syringe and a fixed needle. So, it combines the syringe and needle product codes, QNQ and QNS, precisely the combination of the primary and secondary predicate devices. According to the product code QNQ description, the product could be with or without a needle. However, the primary predicate device is only a syringe with a low dead volume function, not including a needle that is not entirely consistent with the proposed device. So, a secondary predicate device under the product code QNS, "*Low Dead Space Needle, Single Lumen, Hypodermic",* is introduced. It is a kind of low dead space needle similar to the proposed device. Tow predicate devices are combined to demonstrate the safety and effectiveness comparison entirely. Therefore, it does not affect the safety and effectiveness comparison that can be considered substantially equivalent.

#3: Regulation No.

According to note #2, the proposed device is a combination of a low dead volume syringe and a fixed needle. So, it combines the syringe and needle product regulations under regulations No. 21CFR 880.5860 and 21 CFR 880.5570, precisely the combination of the primary and secondary predicate devices. It does not affect the safety and efficacy of the proposed device.

#4: Configuration and material

The difference in the configuration is raised from the structure. The proposed device has a permanent needle attached to the syringe that combines a syringe and a needle. However, the primary and secondary predicate devices are two independent parts. So, the performance testing is run to validate the safety and effectiveness of the proposed devices. Results demonstrate that all performance items meet the requirements listed in standards. Therefore, it is considered substantially equivalent.

The different materials do not affect the effectiveness of the proposed device but affect the safety, especially the biocompatibility performance. Therefore, several testing items are run to validate the biosafety of the proposed device. Biocompatibility results demonstrate no hazard to the human body that complies with ISO 10993 serials standards. Therefore, it is considered substantially equivalent.

#5: Syringe volume

The syringe volume is different from the primary predicate. The syringe volume stands for the dimensions of the syringe barrel, like length and diameter. Professionals select different syringe volumes for different clinical usages, not affecting the intended use. In addition, all the syringe volumes comply with ISO 7886-1. So, the difference in syringe volume does not affect the substantially equivalent of safety and effectiveness.

#6: Needle gauge and length

The needle gauge and length condition is the same as the syringe volume, though the proposed device has a wide range of needle gauge and length than the secondary predicate device. Therefore, the difference in needle gauge and length does not affect the substantially equivalent of safety and effectiveness.

#7: Needle wall type and bevel

The secondary predicate device has a TW needle wall type included in the needle wall type range of the proposed device. Generally, there are four commonly used wall types: RW, TW, ETW and UTW, represented for regular, thin, extra-thin, and ultra-thin, respectively. The proposed device has all kinds of needle wall types with ISO 9626, demonstrating the substantially equivalent of safety and effectiveness.

In addition, the secondary predicate device only mentions that the tip is beveled, not specified LB or SB. LB and SB represented for long bevel (11°±2°) and short bevel (17°±2°). The proposed device has both LB and SB that comply with ISO 9626. So, the needle wall type and bevel should be substantially equivalent of safety and effectiveness.

#8: Sharps prevention function

The proposed device has no sharps prevention function compared with the second predicate device. The safety guard protects the needle-sharp injury to users during discarding needles.

It could enhance the safety of needle usage but not affect the safety and effectiveness of the needle itself. Therefore, it is considered substantially equivalent.

#9: Dead Volume Specification
Compared with the primary and secondary predicate devices, the proposed device has two extra low-dead-space-syringe models, 0.3mL and 0.5L. According to ISO 7886-1, 0.3mL, 0.5mL and 1mL syringes are categorized in the same group (the nominal capacity of syringe V<2mL), which means they follow the same dead space testing standards and acceptance criteria. So it does not affect the substantially equivalent of safety and effectiveness.
The dead space volume data of the proposed device is much lower than the primary predicate device but is similar to the secondary predicate device. However, according to ISO 7886-1, they all meet the same acceptance criteria (max dead space <0.07mL). Besides, the design of low dead space syringe attached with a permanently fixed needle could result in an ultra-low dead space volume, unlike the low dead space syringe with a standard needle (primary predicate) or the standard syringe with a low dead space needle (secondary predicate). The performance bench testing is provided to verify the effectiveness. So it does not affect the substantially equivalent of safety and effectiveness.

9. Non-clinical performance testing

The non-clinical tests of this proposed device are tested in conformance with the following standards.

(1) Physical performance testing:
(a) ISO 7864:2016, Sterile hypodermic needles for single use.
(b) ISO 7886-1:2017 Second edition: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
(c) ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Device.
(d) ISO 6009:2016 Hypodermic needles for single use - Colour coding for identification

(2) Sterility, Shipping, and Shelf-Life
(a) ISO 11135:2014 Sterilization of healthcare products - Ethylene oxide -Requirements for the development, validation and routine control of a sterilization process for medical devices.
(b) ISO 11138-2:2017 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes.
(c) ISO 11737-1:2018, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
(d) ISO 11737-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

(e) ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
(f) ISO 11607-2:2019, Packaging for terminally sterilized medical devices--Part 2: Validation requirements for forming, sealing and assembly processes
(g) ISO 11140-1:2014, Sterilization of health care products —Chemical indicators —Part 1: General requirements
(h) ISO 10993-7:2008/AMD 1:2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants.
(i) ASTM F1140: 2020, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
(j) ASTM F88: 2015, Standard Test Method for Seal Strength of Flexible Barrier Materials
(k) ASTM D3078-2: 2013, Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
(l) ASTM F1929: 2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
(m) ASTM F1980-16, Standard guide for accelerated aging of sterile barrier systems for medical devices
(n) ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

(3) Biocompatibility testing
(a) ISO10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
(b) ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood.
(c) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
(d) ISO 10993-10:2010, Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization.
(e) ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity.
(f) USP 40, <85> Bacterial Endotoxins Test
(g) USP 40, <71> Sterility Test
(h) USP 40, <788>Particulate matter in injection

No clinical testing is available for this device.

10. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The LDV (Low Dead Volume) Syringe is substantially equivalent to the PLPT LDV (Low Dead Volume) Sterile Syringe and EZ Injec LDV

Sterile Safety Needle with respect to indications of use, treatment methods and technical characteristics.