September 29, 2021

Zhuhai DR Medical Instruments Co., Ltd
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K212226
Trade/Device Name: DR Safety Syringe, Sterile Hypodermic needle for Single use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: MEG, FMI
Dated: July 15, 2021
Received: July 16, 2021

Dear Prithul Bom:

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 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)*

Device Name
DR Safety Syringe;
Sterile Hypodermic needle for Single use

Indications for Use *(Describe)*
The DR Safety Syringe is used to inject fluids into or withdraw fluids from the body. In addition, the DR Safety Syringe is designed to aid in the prevention of needle stick injuries.

The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

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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Section 3- 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the guidance The 510(k) Program, 21 CFR 880.5860 and 21 CFR 880.5570.

510(k) Number: K212226

1. **Date of Submission:** August, 06, 2021

2. **Submitter**

Zhuhai DR Medical Instruments Co., Ltd.
Room 502, 5th Floor, Building C, No. 288, Airport East Road, Sanzao Town, Jinwan District,Zhuhai,519000,China
Establishment Registration Number:
Contact Person: Xu Jianhai
Position: Management Representative
Tel.:086-0756-7770668
Email: xujianhai@kdlchina.com

3. **Proposed Device**

510(k) Number: K212226

Trade Name: DR Safety Syringe
Review Panel: General Hospital
Regulation Number: 21 CFR 880.5860
Classification name: Piston Syringe with Safety Syringe
Regulation Class: Class II
Product Code: Safety Syringe: MEG

Trade Name: Sterile Hypodermic needle for Single use
Review Panel: General Hospital
Regulation Number: 21 CFR 880.5570
Classification name: Syringe, Piston
Regulation Class: Class II
Product Code: Safety Syringe: FMI

4. **Predicate device**

a. Predicate device

510(k) Number: K092430
Product Name: InviroSnap Safety Syringe

Review Panel: General Hospital
Regulation Number: 21 CFR 880.5860
Classification name: Piston Syringe with Safety Syringe
Regulation Class: Class II
Product Code: MEG

b. The Secondary Predicate Device

510(k) Number: K190002
Trade Name: Sterile Hypodermic needle for Single use
Review Panel: General Hospital
Regulation Number: 21 CFR 880.5570
Classification name: Syringe, Piston
Regulation Class: Class II
Product Code: FMF and FMI

5. Device description

The DR Safety Syringe is a retractable type piston syringe, designed to aid in the prevention of needle stick injuries. This single-use, disposable syringe provided sterile and consists of the following components for 3ml and 5ml safety syringe: Barrel, Plunger, Stopper, Luer Assembly, hypodermic needle, Locking Ring and O-Ring.
0.5ml and 1ml safety syringe: Barrel, Plunger, Stopper, needle hub, needle tube, protective cap, Locking Ring and O-Ring

The DR Safety Syringe functions in a manner similar to standard syringes for fluid injection/withdrawal. After use, the health care professional fully depresses the plunger to engage the luer assembly/needle hub. Once the luer assembly/needle hub is engaged, pulling back the plunger causes the adapter and the attached needle to be withdrawn into the safety of the barrel. This retraction into the barrel of the syringe can be visually confirmed. Once this safety mechanism has been activated, the syringe is permanently disabled and the needle is completely secured within the barrel. Both the syringe and plunger are discarded in a Sharp's container.

The DR Safety Syringes are available for 0.5mL, 1mL, 3mL, 5mL.

The 0.5ml and 1ml DR Safety Syringes with fixed needle and 3ml, 5ml DR Safety Syringes

with exchangeable needle are used to inject fluids into or withdraw fluids from the body. The DR Safety Syringes are designed to aid in the prevention of needle stick injuries

6. Indications for Use

DR Safety Syringe:
The DR Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the DR Safety Syringe is designed to aid in the prevention of needle stick injuries.

Sterile Hypodermic needle for Single use:
The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

7. Substantially Equivalent comparison

Table 1 Comparison of Technology Characteristics of Sterile Safety Syringe for Single Use

Item	Proposed Device	Predicate Device	Remark
	K212226(Traditional 510K)	K092430 (Traditional 510K)	
Manufacturer	Zhuhai DR Medical Instruments Co., Ltd.	INVIRO MEDICAL DEVICES, INC.	/
Product code	MEG	MEG	Same
Device Classification:	Class II, 21 CFR 880.5860	Class II, 21 CFR 880.5860	Same
Indications for Use	The DR Safety Syringe is used to inject fluids into or withdraw fluids from the body. In addition, the DR Safety Syringe is designed to aid in the prevention of needle stick injuries.	The InviroSnap Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the Inviro Snap Safety Syringe is designed to aid in the prevention of needle stick injuries.	Same
Principle of Operation	After use, the plunger is fully retracted into the barrel providing protection against needle sticks, rendering the device unusable.	After use, the plunger is fully retracted into the barrel providing protection against needle sticks, rendering the device unusable.	Same
Environment of use	Hospital	Hospital	Same
Syringe Volume	0.5ml, 1ml, 3ml, 5ml	1ml, 3ml, 5ml, 10 ml, 20 ml	See comment 1
Needle Gauge	18G-30G	20-23G, 25G, 28-30G	See comment 2
Needle Wall	Regular Wall	Unknown	See comment 2
Device Configuration	Barrel, Plunger, Stopper, Luer Assembly; Hypodermic Needle/needle tube, needle hub, cap; Locking Ring and O-Ring	Barrel, Plunger, Stopper, Luer Assembly, Cannula, cap, Locking Ring and O-Ring	Similar

Tip type	Fixed needle and Luer Lock	Fixed needle and Luer Lock	Same
Material	Barrel, lunger, Locking Ring, Luer Assembly(luer lock), Cap: PP O-Ring: Silicone Stopper: Polyisoprene rubber Needle: Stainless steel: Luer Assembly(Snap Ring): PE Scale line: Ink, Quick-drying water: Lubricant: Silicone oil, Thinning agent	Plunger, Barrel, Cap –Polypropylene Stopper – Santoprene, Thermoplastic Elastomer Needle- Stainless steel	Comment 3
Biocompatibility	• Cytotoxicity • Sensitization Study • Irritation Test/Intracutaneous Reactivity • Systemic Toxicity Studies • Haemolysis test • Pyrogenicity • Complement activity (C3a,SC5b-9) test • In Vivo Thrombogenicity Test	• Cytotoxicity • Sensitization Study • Irritation Test/Intracutaneous Reactivity • Systemic Toxicity Studies • Haemolysis test	Similar, we conduct more test than predicate device, and this difference doesn't raise different questions of safety and effectiveness.
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Method of supply	Sterile and single use	Sterile and single use	Same
Sterilization Method	EO	EO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

Discussion of Technological characteristics

The following differences do not raise different questions of safety and effectiveness,

Comment 1
Differences in syringe volume between the predicate and subject device were addressed through ISO 7886-1 and ISO 7886-4 syringe performance testing.

Comment 2
Differences in needle gauge, wall between the predicate and subject device were addressed through ISO 7864 and ISO 9626 needle performance testing.

Comment 3
Differences in materials between the predicate and subject device were addressed through ISO 10993-1 biocompatibility testing.

Table 2 Comparison of Technology Characteristics of Sterile Hypodermic Needle for Single Use

Item	Proposed Device	The Secondary Predicate Device	Remark
	K212226(Traditional 510K)	K190002 (Traditional 510K)	
Manufacturer	Zhuhai DR Medical Instruments Co., Ltd.	Shanghai Kohope Medical Devices Co., Ltd	/
Product name	Sterile Hypodermic needle for Single use	Sterile Hypodermic needle for Single use	Same
Product code	FMI	FMI	Same
Device Classification	Class II, 21 CFR 880.5570	Class II, 21 CFR 880.5570	Same
Indications for Use	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	Same
Environment of use	Hospital	Hospital	Same
Intended users	Medical professionals and trained care givers	Medical professionals and trained care givers	Same

Operation mode	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	Same
Configuration	Protective cap; Needle tube; Adhesives; Needle hub	Protective cap; Needle tube; Adhesives; Needle hub	Same
Material	Protective cap: PP Needle tube: Stainless steel (SUS304) Adhesives: Epoxy resin Needle hub: PP	Protective cap: PP Needle tube: Stainless steel (SUS304) Adhesives: Epoxy resin Needle hub: PP	Same
Needle Gauge	18G,19G,20G,21G,22G,23G,24G,25G, 26G,27G,28G,29G,30G	18G,19G,20G,21G,22G,23G,24G,25G, 26G,27G,28G,29G,30G	Same
Needle lengths	16mm, 25mm, 38mm	4 – 38 mm	See comment 1
Needle Wall	Regular Wall	Regular wall, thin wall and extra thin wall	Similar
Needle Bevel	17°±2°	Long bevel, short bevel, ultra-treatment bevel	See comment 2
Lubrication Amount/cm2	<0.25mg/cm2	<0.25mg/cm2	Same
Lubricant composition	Silicone Oil	Silicone Oil	Same
Tip Configuration	Angle 27°±3°	Unknown	See comment 2
Needle Cover Dimensions	L: 43±0.5mm, 54.5±0.5mm OD: 8.3±0.1mm/5.8±0.1mm	Unknown	See comment 2
Needle Cover Color	Colorless	Unknown	See comment 3
Delivery Accuracy	Complied with ISO 7864	Complied with ISO 7864	Same
Needle Cover Strength	<15N	Complied with ISO 7864	similar

Hub/Needle Bond Strength	Min 11-69N	Min 11-69N	Same
Color-coded hub	Confirms to ISO6009	Confirms to ISO6009	Same
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Method of supply	Sterile and single use	Sterile and single use	Same
Sterilization Method	EO	EO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

Discussion of Technological characteristics
The following differences do not raise different questions of safety and effectiveness,

Comment 1: The predicate device includes additional needle length compared to the subject device. The needles are tested in accordance with ISO 7864 and released in accordance with the standards compliance. This was verified by performance testing according to ISO 7864.

Comment 2: As to Needle Bevel, Tip Configuration, Needle Cover Dimensions, we can't get the specific information about predicate device, The needles are tested in accordance with ISO 7864 and released in accordance with the standards compliance. This was verified by performance testing according to ISO 7864.

Comment 3: Needle Cover for the proposed device is unpigmented, the color of which is colorless, we can't get the specific color of the predicate device' needle cover, the needle covers are tested in accordance with ISO 7864 and released in accordance with the standards compliance. This was verified by performance testing according to ISO 7864.

8. The results of the comparison

DR Safety Syringe is substantially equivalent in indication for use, design, raw material, sterilization method to the predicate devices, InviroSnap Safety Syringe. The sterile hypodermic needle for the proposed device is substantially equivalent in indication for use, design, raw material, sterilization method to the predicate devices. The differences in raw material and needle between the devices do not raise new issues of safety and effectiveness.

9. Sterilization and Shelf Life

Sterilization and Shelf Life Testing were performed on the proposed device:

Microbiological Performance qualification (MPQ)	ISO11135:2014
Physical Performance qualification (PPQ)	ISO11135:2014
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Microbial barrier test	ASTM F1608
Seal Strength test	ASTM F 88
Seal leak test	ASTM F 1929
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device.

10. Clinical Test

No clinical study is included in this submission.

11. Performance data

All necessary bench and non-clinical testing were conducted on DR Safety Syringe to support a determination of substantial equivalence to the predicate devices.
The non-clinical, bench testing are conducted according to ISO 7886-1 and ISO 7886-4, USP 788, ISO 23908 and FDA guidance titled: “Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff,” included:

1 Appearance
2 Tolerance on graduated capacity
3 Graduated scale
4 Barrel
5 Plunger stopper/plunge
6 Syringe needle
7 Liquid leakage
8 Air leakage

9 Syringe with Luer nozzle
10 Dead space
11 Re-use prevention feature test
12 Limits for acidity or alkalinity
13 Limits for extractable metals
14 EO residual
15 Sterility
16 Bacterial Endotoxin (LAL test)
17 Testing activation of a sharps injury protection feature
18 Particulate test,
19 ECH residual

All necessary bench and non-clinical testing were conducted on Fixed needle to support the performance of the needle in safety syringe.
The non-clinical, bench testing are conducted according to ISO 9626 included:
1 Appearance
2 Dimensions of tubing
3 Stiffness
4 Bond between hub and needle tube
5 Resistance to breakage
6 Limits for acidity or alkalinity
7 Corrosion resistance

All necessary bench and non-clinical testing were conducted on proposed sterile hypodermic needle to support a determination of substantial equivalence to the predicate devices.
The non-clinical, bench testing are conducted according to ISO 7864 included:
1 Appearance
2 Colour coding
3 Tolerances on length
4 Bond between hub and needle tube
5 Patency of lumen
6 The penetration force and drag force for needles
7 Limits for acidity or alkalinity
8 Limits for extractable metals

12. Biocompatibility Testing Summary

Biocompatibility testing was conducted in compliance with ISO 10993-1, for externally communicating devices with limited exposure (<24 hours) to blood path, direct, and included below test items.

Table 1 Biocompatibility tests

Items	Standards	Conclusion
In Vitro Cytotoxicity	ISO 10993-5:2009	Under the conditions of this study, the test article Micro catheter extract did not show potential toxicity to L-929 cells.
Intracutaneous reactivity	ISO 10993-10:2010	The test results showed that the polar and non-polar test article extracts did not induce intracutaneous reactivity in rabbit under the test condition.
Skin Sensitization	ISO 10993-10:2010	No evidence of causing skin sensitization
Acute System Toxicity	ISO 10993-11:2017	Under the conditions of this study, there was no evidence of systemic toxicity from the extracts, the test article extract met the requirements of this study.
Pyrogenicity	ISO 10993-11:2017	No rabbit an individual rise in temperature of 0.5℃ or more.
In Vitro hemolytic	ASTM F756-17	The test result showed the Micro catheter had no influence on hemolytic properties.
Complement activity (C3a,SC5b-9) test	ISO 10993-4:2017	Under the conditions of this study, the test article safety syringe had no effect on complement activity.
In Vivo Thrombogenicity Test	ISO 10993-4:2017	Under the conditions of this study, the test article safety syringe meets the requirement of thrombogenicity test.

The subject device, DR Safety Syringe is subject to biocompatibility test in accordance with ISO 10993-1, the test result demonstrate that DR Safety Syringe is safe.

13. Conclusion

The nonclinical tests demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.