January 31, 2020

Guangdong Haiou Medical Apparatus Stock Co., Ltd
Mr. Salon Chen
System Engineer
GHTF Medical & Drug Technology Services Institutions
Tianbao Office Room 225, Sha Tai Road No. 209
Baiyun District of Guangzhou, Guangdong Province
CHINA

Re: K141349
Trade/Device Name: Disposable sterile needle retractable safety syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG
Dated: February 10, 2015
Received: March 12, 2015

Dear Salon Chen:

This letter corrects our substantially equivalent letter of April 10, 2015.

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 -S

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

K141349

Indications for Use

510(k) Number (if known):
Device Name: Disposable sterile needle retractable safety syringe

Indications for Use:

Disposable sterile needle retractable safety syringe is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into patient.

Prescription Use___V_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

K141349

The date the summary was prepared: on April10, 2015

This 510(k) Summary of 510(k) is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1. Basic Information

- Company Name: Guangdong Haiou Medical Apparatus Stock Co., Ltd
- Establishment Registration Number: Not registered yet
- Address: Mazha Industrial Area, Liusha town, Puning city, Guangdong province, China,518034
- Phone:+86-663-2900999
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- Contact Person(Title):Jacky (General Manager)
- E-mail：qc@haiou.net.cn

2. Application Correspondent

- Company Name: GHTF Medical & Drug technology service institutions
- Address: : Tianbao office room 225,Sha Tai Road No.209, Baiyun District of Guangzhou City, Guangdong Province, China
- Phone: +86-020-66228028
- Fax: +86-020-62809168
- Contact Person(Title):Salon Chen
- E-mail：33999439@qq.com

3. Subject Device Information:

- Product Code: MEG
- Regulation Number:880.5860
- Class:2
- Classification Name: Piston Syringe
- Trade Name: Disposable sterile needle retractable safety syringe

Predicate Devices:

510K Number	Submitted Device	Manufacturer	Syringe type	Product Code
K113587	Automatically Retractable Safety Syringe(With Fixed Needle)	Shantou Wealy medical instrument Co., Ltd.	Anti-stick syringe	MEG

4. Device Description

Disposable sterile needle retractable safety syringe is a piston syringe. The device is intended for medical purposes and consists of a protective cover, Needle, Needle base, circle ring, Pull & back

part, Piston, Plunger and barrel. The needle is fixed on the syringe. The device is used to inject fluids into the body.

The subject device of Disposable sterile needle retractable safety syringe is available in 0.5ml, 1ml, 3ml, 5ml and 10 ml volumes.

The subject device is provided sterilized.

Disposable sterile needle retractable safety syringe works like a conventional hypodermic syringe except for its ability to retract the contaminated needle inside of the syringe immediately after patient injection. Needle retraction is activated by the syringe user. After the injection is completed, the groove of the upper end of the plunger locks the needle. The plunger is retracted completely after the injection. The needle is retracted completing into the barrel of the syringe.

5. Intended use

Disposable sterile needle retractable safety syringe is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into patient.

6. Performance Summary

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

ISO 7886-1:1993, Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
ISO 7886-4:2006, Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature
ISO 10993-1:2009 Biological evaluation of medical devices-Parts 1: Evaluation and testing
ISO 10993-4:2002 Biological evaluation of medical devices-Parts 4: Selection of test for interactions with blood
ISO 10993-5:2009 Biological evaluation of medical devices-Parts 5: Tests for In Vitro cytotoxicity
ISO 10993-7:2008 Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals.
ISO 10993-10:2010 Biological evaluation of medical devices-Parts 10: Tests for irritation and skin sensitization
ISO 10993-11:2006 Biological evaluation of medical devices-Parts 11: Tests for systemic toxicity
ISO11607 -1:2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems.
ISO11607 -2:2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ISO11135:2007 Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO11737- 1:2006 Sterilization of medical devices -- Microbiological methods -Part 1: Determination of a population of microorganisms on products

ISO9626-1991Stainless steel needle tubing for the manufacture of medical devices-Apparatus, confirmatory test arrangement and guidance

ASTM-F1980-2002 Standard Guide for Accelerated Aging of Sterile Medical Device Packages

ASTM F1929-1998 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

7. Comparison to Predicate Device

Comparison with predicate devcie----the below the comparison table

Elements of Comparison	Predicate Device	Subject Device
Company Name	Shantou Wealy medical instrument Co., Ltd.	Guangdong Haiou Medical Apparatus Stock Co., Ltd
510K Number	K113587	N/A
Device Name	Automatically Retractable Safety Syringe (With Fixed	Disposable sterile needle retractable safety syringe
Product Code	MEG	Same
Regulation No.	880.5860	Same
Syringe type	Anti-stick syringe	Same
Class	2	Same
Intended use	Automatically Retractable Safety Syringe (With Fixed Needle) is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient	Same
Nozzle Type	Fixed Needle	Same
Specific drug use	Conventional drugs	Same
Needle type	Tri-Beveled Tip	Same
Reuse	Non-reusable	Same
Lubricant Composition	Polydimethylsiloxane（PDMS）	Same

Barrel marking specs	Scale: conforms to ISO 7886-1:1993/Corrigendum1:1995	Same
Needle cover-color	colorless	Same
Barrel transparency	Clear	Same
Volume	5ml	**0.5ml, 1ml, 3ml,5ml,10ml(Analysis1)**
Performance Testing	Conform to ISO 7886-1:1993/Corrigendum	**Conform to ISO 7886-1:1993/Corrigendum 1:1995 and ISO7886-4:2006**
Material	Barrel—PP	Same
	Plunger--PP	Same
	Protective cover--PP	Same
	Needle base--PP	Same
	N/A(Analysis2)	Circle ring-- Silica gel
		Pull & back part-- ABS
	Piston-- Polypropylene rubber	Same
	Needle--SUS	Same
Biocompatibility	Conform to the requirement of ISO 10993 series Standards	Same
Cytotoxicity	No Cytotoxicity	Same
Irritation	No intracutaneous reactivity	Same
Sensitization	No delayed dermal contact sensitization	Same
Sterilization	SAL--10^6	Same
	Method--EO	Same
	Validation-- Conforms to ISO 11135	Same
	Package Integrity-- Conforms to ISO 11607	Same
	EO Residual-- Conforms to ISO 10993-7	Same
	pyrogen free	Same

Analysis 1:
The subject device has only five kinds of volumes which are 0.5ml, 1ml, 3ml, 5ml and 10ml while the predicate device has only one kind of volume which is 5ml. The difference in the volume will not affect the function. So the difference of the volume will not affect the safety and effectiveness of the subject device.

Analysis 2:
The subject device and the predicate device are same in structure. Only subject device detailed described two parts with Circle ring and pull & back part, circle ring is the role of the sealing function and prevents leakage, pull & back part is the role of retractable gravitation.

Compared with predicate devices, the subject devices are very similar in design principle, intended use, indication for use functions, material and the applicable standards. The differences between subject devices and predicate devices do not raise any new questions of safety or effectiveness.

8. Conclusion

The subject device has the same functional features as the predicate. The differences in the safety feature mechanism of action and the syringe sizes do not raise new questions of safety or effectiveness in the subject device, thus the subject devices are substantially equivalent to the predicate.