DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 3, 2017

Shanghai Kindly Medical Instruments Co.,ltd.
Jeffery Hui
Official Correspondent
No. 925 Jinyuan Yi Rd
Shanghai, 201803 CN

Re: K170025
Trade/Device Name: Angiography Syringe (Fixed Adapter), Angiography Syringe (Rotating Adapter)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: August 3, 2017
Received: September 7, 2017

Dear Jeffery Hui:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170025

Device Name
Angiography Syringe (Fixed Adapter), Angiography Syringe (Rotating Adapter)

Indications for Use *(Describe)*
The Angiography syringe is used to inject contrast media into the heart, great vessels, and coronary arteries during angiographic procedures.

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 Ⅲ-510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the guidance The 510(k) Program and 21 CFR 807.92.

510(k) Number: K170025

1. **Date of Submission:** Aug.03, 2017

2. Submitter

Shanghai Kindly Medical Instruments Co., Ltd.
No. 925, Jinyuan yi Road, Shanghai, 201803, China
Establishment Registration Number: 3009605245
Contact Person: Xu Jianhai
Position: RA Supervisor
Tel.: +086-021-59140056
Fax: +086-021-59140056
Email: xujianhai@kdlchina.net

3. Proposed Device

Proposed Device Name: Angiography Syringe (Fixed Adapter), Angiography Syringe (Rotating Adapter)
Proposed Device Model: 6mL, 8mL, 10mL, 12mL.
Classification: Class II
Classification Name: Angiographic injector and syringe
Product Code: DXT
Regulation Number: 21 CFR 870.1650
Review Panel: Cardiovascular

4. Predicate device

a. 510(k) Number: K093830

Product Name: Medline Angiographic Control Syringe

Manufacturer: Medline Industries Inc.

5. Device description

The Angiography Syringe are plastic , single-use, disposable syringes to be offered in 6ml, 8ml, 10ml, 12ml size. As manual control syringe, each configuration includes bilateral, external finger rings located on the proximal barrel shaft. The proximal thumb rings located on the plunger, in tandem with the external finger rings on the barrel, allows for single handed movement to create aspiration and/or expulsion of fluids. The angiography syringe has two tip fitting: fixed adapter and rotating adapter

6. Intended Use Statement:

The Angiography syringe is used to inject contrast media into the heart, great vessels, and coronary arteries during angiographic procedures.

7. Non-clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all device specification as were substantially equivalent (SE) to the predicate device. The test result demonstrates that the proposed devices comply with the following standards:

ISO 594-1:1986 Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 1: General Requirements.

ISO 594-2:1998 Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings

ISO 7886-1:1993 Sterile hypodermic syringes for single use - Part 1: Syringes for manual.

Biocompatibility testing and reference standards:

1) In Vitro Hemolytic -- ASTM F 756-13 standard Practice for Assessment of Hemolytic Properties of Materials.

2) In Vitro Cytotoxicity -- ISO 10993-5:2009, Biocompatibility Evaluation of Medical Device - Part 5: Tests for In Vitro Cytotoxicity.

3) Skin Irritation -- ISO 10993-10:2010, Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Shin Sensitization.

4) Skin Sensitization -- ISO 10993-10:2010, Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Shin Sensitization.

5) Acute Systemic Toxicity -- ISO 10993-11:2006, Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity.

6) Pyrogen -- ISO 10993-11:2006, Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity.

8. Clinical Test

It is not applicable.

9. Summary Comparing the Technological Characteristics

The proposed device and predicate device have the same classification information, same material, principle of operation and syringe tip style. The proposed device has four kinds of volumes, while the predicate has various sizes. So the volume range of the proposed device is included in the volume range of the predicate device. Therefore, they are considered to be substantial equivalent in the volume aspect.

Item	Proposed Device	Predicate Device(K093830)	Remark
Product Code	DXT	DXT	SE
Regulation No.	870.1650	870.1650	SE
Class	II	II	SE
Intended Use	The Angiography syringe is used to inject contrast media into the heart, great vessels, and coronary arteries during angiographic procedures.	An angiography syringe is a device that consist of a syringe which is used to inject contrast material into the heart, great vessels, and coronary arteries during angiographic or CT procedures.	SE
Principle of Operation	It is designed for single manual use. The plunger is free to move. When pulled the plunger to aspirate the fluid or pushed it to injection.	It is designed for single manual use. The plunger is free to move. When pulled the plunger to aspirate the fluid or pushed it to injection.	SE
Components	Barrel, piston, plunger, plunger cap, rotating adapter, O-ring, thumb ring	Barrel, piston, plunger, plunger cap, Rotating connector, O-ring thumb ring	SE
Conical fitting	Comply with ISO ISO 594-1:1986 ISO 594-2:1998	Comply with ISO ISO 594-1:1986 ISO 594-2:1998	SE
Where used	Hospital	Hospital	SE
Size	6mL,8mL,10mL,12mL	Various size	Similar
Syringe tip style	Fixed adapter and rotating adapter	LL connector and rotating connector	SE

10.Conclusion

The proposed device, angiography syringe, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, and test protocols. The angiography syringe is substantially equivalent to the legally market predicate device.