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 6, 2017

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

Re: K170014
Trade/Device Name: High Pressure Tubing
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170014

Device Name
High Pressure Tubing

Indications for Use *(Describe)*
The High Pressure Tubing is indicated for use as a connecting line for injection of contrast media or saline during coronary 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary - K170014

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: K170014

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

2. **Submitter**

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3. **Proposed Device**

Proposed Device Name: High Pressure Tubing
Proposed Device Model: 30cm, 60cm, 90cm, 120cm, 150cm,
Classification: Class II
Product Code: DXT
Classification Name: Angiography Injector and Syringes
Regulation Number: 21 CFR 870.1650
Review Panel: Cardiovascular

4. **Predicate device**

a. 510(k) Number: K140356

Product Name: Sunmed^{TM} High Pressure Line

Manufacturer: Sunny Medical Device (Shenzhen) Co., Ltd.

5. Device description

The High Pressure Tubing is a sterile, single use device which can withstand injection pressure to 1200psi.

The High Pressure Tubing is composed of tubing with connector at each end. The connector is a female-male combination and rotating adapter.

The High Pressure Tubing is supplied sterile by Ethylene Oxide and disposable device. The material of tube is PU with polyamides liner, and the appearance is braided.

6. Indications for Use Statement:

The High Pressure Tubing is indicated for use as a connecting line for injection of contrast media or saline during coronary 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 8536-4:2010, Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed.

8. Clinical Test

It is not applicable

9. Summary Comparing the Technological Characteristics

The predicate device was compare in the following areas and found to have identical technological characteristic.

Item	Proposed Device	Predicate Device K140356	Remark
Class	II	II	Same
Intended Use	The High Pressure Tubing is indicated for use as a connecting line for injection of contrast media or saline during coronary angiographic procedures.	The sunmed™ high pressure line is used as a connecting line for injection of a contrast, saline or other diagnostic fluids (by connecting the female luer of high pressure with an angiography syringe and connecting the male luer or rotating male luer of high pressure with the catheter) during coronary angiography procedures. This product is composed of female luer, male luer (including rotating male luer), and tubing and with or without caps.	Same
Operating principle	Manual connect the male luer or rotating male luer of high pressure with other catheter device.	Manual connect the male luer or rotating male luer of high pressure with other catheter device.	Same
Pressure Rating	1200psi	500psi, 900psi, 1200psi	Similar
Conical fitting	Comply with ISO 594-1:1986, ISO 594-2:1998	Comply with ISO ISO 594-1:1986, ISO 594-2:1998	Same
Components	Tubing, female/male luer, rotating adapter	Female luer, male luer (including rotating luer), and tubing and with or without caps.	Same
Flexible	Yes	Yes	Same
Design	Designed to multiple length and connector types. PU tubing with polyamides liner for 1200psi	Designed to multiple length and connector types. PU tubing with Nylon liner for 1200psi and PVC tubing for 500psi.	Similar
Size	30cm,60cm,90cm,120cm,150cm,	30cm,50cm,60cm,90cm,75cm,100cm,120cm,150cm,200cm	Same
Package material	Dupont Tyvek Medical paper-plastic pouch,	Medical paper-plastic pouch, Tyvek plastic pouch	Same

10. Conclusion

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