DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
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: K170024
Trade/Device Name: Y-connector Kit
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, Or Fitting
Regulatory Class: Class II
Product Code: DTL, DQX
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)*
K170024

Device Name
Y-Connector Kit

Indications for Use *(Describe)*
Y-Connector hemostasis valve is intended to minimize blood loss during the introduction, withdrawal and use of devices that have an outer diameter of 8F catheter during diagnostic and interventional procedures.

The Insertion Tool facilitates introduction of a guidewire through the Y-Connector and into the guiding catheter.

The Torque Device attaches to guidewires and provides a handle to assist in manipulation of the guidewire.

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.

Section Ⅲ- 510(k) Summary

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

510(k) Number: K170024

1. **Date of Submission:** Sep.15, 2017

2. **Submitter**

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3. **Proposed Device**

Proposed Device Name: Y-connector Kit
Proposed Device Model: YCK113
Classification: Class II
Product Code: DTL&DQX
Regulation Number: 21 CFR 870.4290, 21 CFR 870.1330
Classification Name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass and catheter guide wire
Review Panel: Cardiovascular

4. **Predicate device**

a. 510(k) Number: K042060

Product Name: EasyPass™ US Y-connector Hemostatic Valve

Manufacturer: Millimed A/S

Product code: DTL&DQX

Regulation Number: 21 CFR 870.4290, 21 CFR 870.1330

5. Device description

The Y-connector kit is single use disposable device. It including Y connector, Insertion tool and torque device. It is mainly use for PTCA or PTA procedures to create the entrance and minimize blood loss when intervention device are inserted into the human vascular system.

The Y connector with a rotating luer lock, a sidearm and a hemostasis valve that is designed to provide a port for interventional system. The seal of hemostasis valve can be opened by pushing the switch cap, and closed by releasing switch cap.

The insertion tool is used to facilitate placement of a guide wire tip through the Y connector.

The torque device is designed to hold the guide wire and provide a handle for manipulating, so the doctor can control the guide wire to the right position.

6. Intended Use Statement:

Y-Connector hemostasis valve is intended to minimize blood loss during the introduction, withdrawal and use of devices that have an outer diameter of 8F catheter during diagnostic and interventional procedures.

The Insertion Tool facilitates introduction of a guidewire through the Y-Connector and into the guiding catheter.

The Torque Device attaches to guidewires and provides a handle to assist in manipulation of the guidewire.

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.

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

Comparisons of the proposed and predicate devices show that the technological characteristics are identical or substantially equivalent to the currently marked predicate devices.

Item	Proposed Device	Predicate Device K042060	Remark
Product Code	DTL DQX	DTL DQX	SE
Regulation No.	870.4290, 870.1330	870.4290, 870.1330	SE
Class	II	II	SE
Intended Use	Y-Connector hemostasis valve is intended to minimize blood loss during the introduction, withdrawal and use of devices that have an outer diameter of 8F catheter during diagnostic and interventional procedures. The Insertion Tool facilitates introduction of a guidewire through the Y-Connector and into the guiding catheter. The Torque Device attaches to guidewires and provides a handle to assist in manipulation of the guidewire.	The EasyPassTM US Y-connector Hemostatic Valve is intended to maintain hemostasis during the introduction, use and withdrawal of diagnostic and interventional devices that have an outer diameter of 7 French or smaller. The guide wire insertion tool facilitates introduction of the guide wire through the hemostasis valve and into the guiding catheter. The torque device, inserted over the proximal end of the guide wire, provided a handle for easier manipulation of the guide wire.	SE
Principle of Operation	By manual operation	By manual operation	SE
Components	Y-connector, insertion tool torque device	Y-connector, insertion tool torque device	SE
Conical fitting	Comply with ISO 594-1:1986 ISO 594-2:1998	Comply with ISO ISO 594-1:1986 ISO 594-2:1998	SE
Design	The Y connector with a rotating luer lock, a sidearm and a hemostasis valve with push-rotate mechanism. The seal of hemostasis valve can be opened by pushing-rotating the switch cap, and closed by pulling-rotating switch cap.	To open the hemostasis valve, a valve opener cap with a center passage tube is pushed distally. The hemostasis valve is closed by pulling the valve opener cap proximally.	Analysis 1
Where used	Diagnostic and interventional procedures	Diagnostic and interventional procedures	SE

10.Conclusion

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