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 6, 2017

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

Re: K170027
Trade/Device Name: Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: MAV
Dated: September 5, 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,

for Kenneth J. Cavanaugh -S

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)*
K170027

Device Name
Inflation Device

Indications for Use *(Describe)*
The inflation device is intended to be used in PTCA or PTA procedures to create and monitor pressure in the balloon and to deflate the balloon dilatation catheter.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary - K170027

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: K170027**

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: Inflation Device
Proposed Device Model: AI25
Classification: Class II
Classification Name: Angiographic Injector And Syringe
Regulation Number: 21 CFR 870.1650
Review Panel: Cardiovascular
Product Code: MAV

4. **Predicate device**

a. 510(k) Number: K102648
Product Name: ANT Inflation Device/ ANT Inflation Device Compact Pack
Manufacturer: Shenzhen ANT Hi-Tech Industrial Co., Ltd.

5. **Device description**

The inflation device consists of barrel, threaded plunger assemble with a handle, a trigger, pressure gauge, an outer shell assembly that retains the internal components, and a pressure connecting tubing with rotating adapter. Also enclosed is a stopcock to aid in preparation and use of device. The inflation device is 20 mL disposable device capable of producing a maximum pressure of 30 atm.

The inflation device is sterilized by EO.

## 6. Indications for Use Statement:

The inflation device is intended to be used in PTCA or PTA procedures to create and monitor pressure in the balloon and to deflate the balloon dilatation catheter.

## 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.

## 8. Clinical Test

It is not applicable.

## 9. Summary Comparing the Technological Characteristics

The proposed device and predicate device have the same classification information, intended use, principle of operation, design and Volume and pressure range. The proposed device and the predicate's material have a little difference, and the whole device has been tested for material biocompatibility, the test result demonstrated that the device comply with the requirements of a series ISO 10993 standards.

Table Ⅲ-1 General information Comparison

| Item | Proposed Device | Predicate Device K102648 | Remark |
|---|---|---|---|
| Product Code | MAV | MAV | SE |
| Regulation No. | 21 CFR.870.1650 | 21 CFR.870.1650 | SE |
| Class | Class Ⅱ | Class Ⅱ | SE |
| Intended Use | The inflation device is intended to be used in PTCA or PTA procedures to create and monitor pressure in the balloon and to deflate the balloon dilatation catheter. | The ANT inflation device is intended for use during vascular procedures in conjunction with interventional device such as balloon catheters to create and monitor pressure in the balloon catheter. | SE |

Table Ⅲ--2 Performance Comparison

| Item | Proposed Device | Predicate Device K102648 | Remark |
|---|---|---|---|
| Principle of Operation | The plunger is free to move when the trigger is pushed down. In this position you may pull the plunger to aspirate or push it to inject for a quick fill. Release the trigger to lock the plunger. To add and hold pressure in increments, turn the handle clockwise with the trigger in the up position. Press the trigger down and pull back on the plunger to deflate. | The plunger is free to move when the trigger is pushed down. In this position you may pull the handle to aspirate or push it to inject for a quick fill. Release the trigger to lock the plunger. To add and hold pressure in increments, turn the handle clockwise with the trigger in the up position. Press the trigger down and pull back on the handle to deflate. | SE |
| Components | A barrel, a plunger, a trigger, shell, a piston, a pressure gauge, a tubing, a rotating adapter and stopcocks | A barrel, a plunger with handle, a trigger, shell, a piston, a pressure gauge, a tubing, a rotating adapter and stopcocks | Similar Analysis 1 |

| | | | |
|---|---|---|---|
| | | ANT Inflation Device compact Pack: a hemostasis, a torque device and a wire introducer. | |
| Conical fitting | Conforms to ISO 594-1:1986 or ISO 594-2:1998 | Conforms to ISO 594-1:1986 or ISO 594-2:1998 | SE |
| Design | 1. The 20mL barrel is made of polycarbonate for clarity and added strength against high system pressure.<br>2. The threaded plunger assembly with a handle is made of high impact resistant polyamides.<br>3. Controlled inflation and deflation is achieved by manually pushing handle and press the trigger.<br>4. High-pressure polyurethane tubing with polyamides provides links from the inflation barrel to the angiographic catheter using a 6% conical locking connector. | 1. The 20mL barrel is made of polycarbonate for clarity and added strength against high system pressure.<br>2. The pressurization system and the plunger are made of high impact resistant polypropylene.<br>3. Controlled inflation and deflation is achieved by manually pushing or pulling the plunger and press the trigger.<br>4. High-pressure polyurethane tubing provides links from the inflation barrel to the angiographic catheter using a 6% conical locking connector. | SE |
| Where used | PTCA | PTCA | SE |
| Volume and pressure range | 20 mL, 0~30ATM | 20 mL, 0~30 ATM | SE |

Table Ⅲ-3 Safety Comparison

| Item | | Proposed Device | Predicate Device K102648 | Remark |
|---|---|---|---|---|
| Material | | PC, PA+PU, ABS, PC alloy, Steel, Silicon rubber, PA, rubber | PA, PC, PU etc. | Similar Analysis 2 |
| Biocompatibility | | Conforms to the requirements of ISO 10993 series Standards | Conforms to the requirements of ISO 10993 series Standards | SE |
| In Vitro Hemolytic | | No hemolysis | No hemolysis | SE |
| Acute Systemic Toxicity | | No Acute Systemic Toxicity | No Acute Systemic Toxicity | SE |
| In Vitro Cytotoxicity | | No cytotoxicity | No cytotoxicity | SE |
| Skin Irritation | | No intracutaneous reactivity | No intracutaneous reactivity | SE |
| Skin Sensitization | | No Sensitization | No Sensitization | SE |
| Sterilization | SAL | $10^{-6}$ | $10^{-6}$ | SE |
| | Method | EO Sterilization | EO Sterilization | SE |
| | Validation | Conforms to ISO 11135 | Conforms to ISO 11135 | SE |

| | | | | |
|---|---|---|---|---|
| | Package Intergrity | Conforms to ISO 11607 | Conforms to ISO 11607 | SE |
| | EO Residual | Conforms to ISO 10993-7 | Conforms to ISO 10993-7 | SE |
| | Pyrogen | Non-pyrogenic | Non-pyrogenic | SE |
| Label and labeling | | Conforms to FDA Requirements | Conforms to FDA Requirements | SE |

## 10. Conclusion

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