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

December 12, 2014

Sunny Medical Device (Shenzhen) Co., Ltd.
c/o James Qi Zhang
56 Lehigh Aisle
Irvine, CA 92612

Re: K133795
Trade/Device Name: Sunmed™ Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: MAV
Dated: September 17, 2014
Received: November 10, 2014

Dear Mr. Zhang:

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" (21CFR 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 yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

Indications for Use

510(k) Number (if known): K133795

Device Name: Sunmed^{TM} Inflation Device

Indications for Use:

The Sunmed^{TM} Inflation Device is a set of accessorial device. It is composed of an inflation device, and may be composed of a stopcock and a hemostatic valve. The inflation device is intended for use in PTCA or PTA procedures to create and monitor pressure (by connecting the rotating male luer of inflation device with the balloon catheter's female luer) in the balloon and to deflate the balloon. The hemostatic valve is recommended for use during PTCA or PTA procedures in conjunction and/or diagnostic device (e.g. balloon dilatation catheters).Stopcock is used to release and purge any trapped air (if used).

Prescription Use ✘ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

3. 510(k) Summary

1. Submitted by: Sunny Medical Device (Shenzhen) Co., Ltd.

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Contact: JamesQi Zhang, General Manager

E-mail: jamesqizhang@gmail.com

Date: Sep17, 2014

2. Proposed Device:

Trade/Proprietary Name: Sunmed™ Inflation Device

Common/Usual Name: Disposable Inflation Device

Classification: II

Classification Name: Angiographic injector and syringe

Regulation Number: 870.1650

Product Code: MAV

3. Predicate Device:

510(k) Number	Trade or Proprietary or Model Name	Manufacture
K102648	ANT Inflation Device/ ANT Inflation Device Compact Pack	Shenzhen ANT Hi-Tech Industrial Co., Ltd.
K032840	Atrion Medical QL® Inflation Device	Atrion Medical Products, Inc.

4. Device description

The Sunmed™ Inflation Device is a set of accessorial device. It is composed of an inflation device, and may be composed of a stopcock and a hemostatic valve. The inflation device is 30ml disposable device capable of producing a maximum pressure of 40ATM. Pressure can be monitored via a pressure gauge. The manually operation of the device is achieved by the manipulation of a large handle to drive a piston housed within the body of the device.

Hemostatic valve is a single Y connector, and may be composed of an insertion tool, and a torquer. The hemostasis valve is designed to provide a port for interventional system. The insertion tool is used to facilitate placement of a guide wire tip through the hemostasis valve. The torque device is designed to hold the guide wire and provide a handle for manipulating.

5. Intended Use

The Sunmed™ Inflation Device is a set of accessorial device. It is composed of an inflation device, and may be composed of a stopcock and a hemostatic valve. The inflation device is intended for use in PTCA or PTA procedures to create and monitor pressure (by connecting the rotating male luer of inflation device with the balloon catheter's female luer) in the balloon and to deflate the balloon. The hemostatic valve kit is recommended for use during PTCA or PTA procedures in conjunction and/or diagnostic device (e.g. balloon dilatation catheters). Stopcock is used to release and purge any trapped air (if used).

6. Technological Comparison to Predicate Device

The proposed device will use technology that is similar to the technology already in use by Shenzhen ANT Hi-Tech Industrial Co., Ltd. and Atrion Medical Products, Inc. The maximum pressure of the proposed device is the same as The Atrion Medical QL® Inflation Device. It has the same intended use, fundamental concepts and principles of operation as the ANT Inflation Device .The proposed device uses the same materials, packaging and sterilization method like each of the predicate devices.

A detailed comparison of technological characteristics with the predicate devices is included insubstantial equivalence of the submission.

7. Summary of Non-Clinical Testing

The following tests were performed on the Sunmed™ Inflation Device:

Biocompatibility Testing:

Pyrogen Test

Endotoxin Test

Acute Systemic Toxicity Test(two kinds of solvent)

Intracutaneous Reactivity Test

In Vitro Cytotoxicity Test

Skin sensitization Test (two kinds of solvent)

In Vitro Hemolysis Study

Complement Activity Test (C3a, SC5b-9)

In Vivo Thrombogenicity

Package Penetrate Testing

Asepsis Testing

Aging Testing

EtO and ECH Residue Testing

Bench Testing

8. Clinical Evaluation was not applicable.

9. Conclusions

Based on the information presented in this 510(k) premarket notification, the Sunmed™ Inflation Device is considered substantially equivalent to the ANT Inflation Device and Atrion Medical QL® Inflation Device.