DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 10, 2016

Sunny Medical Device (Shenzhen) Co., Ltd.
James Qi Zhang
General Manager
56 Lehigh Aisle
Irvine, California 92612

Re: K160190
Trade/Device Name: Sunmed Control Syringes
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: September 28, 2016
Received: October 3, 2016

Dear James Qi 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" (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 yours,

Brian D. Pullin -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)*
K160190

Device Name
Sunmed Control Syringes

Indications for Use *(Describe)*
The Sunmed Control Syringes is intended to inject contrast media or saline for 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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5. 510(k) Summary（K160190）

1. Submitted by: Sunny Medical Device (Shenzhen) Co., Ltd.
   Registered Address: 4/F and 5/F, Dongpingxing Creative Science Park, Longgang District, Shenzhen, Guangdong, P.R. China 518172
   Contact Address: 56 Lehigh Aisle, Irvine, CA 92612

   Telephone: (949)216-8838
   Fax: (949)423-0168
   Contact: JamesQi Zhang, General Manager
   E-mail: jamesqizhang@gmail.com
   Date: November 9, 2016

2. Proposed Device:
   Trade/Proprietary Name: Sunmed™ Control Syringes
   Common/Usual Name: Control Syringes
   Classification: II
   Classification Name: Angiographic injector and syringe
   Regulation Number: 870.1650
   Product Code: DXT

3. Predicate Device:

510(k) Number	Trade Name	Manufacture
K093830	Medline Angiographic Control Syringes	Medline Industries Inc.
K072696	ANT Angiographic Syringes	Shenzhen Ant Hi-Tech Industrial Co., Ltd.

Note: In the case of other characteristics substantially the same, Mediline Angiographic Control Syringes and our company's product are more similar in the specification model and materials. Medline Angiographic Control Syringes is identified as the primary predicate, which manufactured by Medline Industries Inc.

4. Device description

The Sunmed™ Control Syringes using dynamics principle, by means of the interference fit between the plunger with piston and the barrel, using the aspirating or driving force generated by manual function to draw or inject angiography medicament or saline for clinical disposable use.

The Sunmed™ Control Syringes is a single-use device that consists of two different structures: one is the standard type; the other is locking plunger type. The properties of the standard plunger type and locking plunger type are in table below:

Standard plunger Type	Locking Plunger Type
Humanized design, easy and simple operation, can be single hand operation	Humanized design, easy and simple operation, can be single hand operation
The wall of the tube is clear and transparent, the inner surface is smooth, and the promotion is convenient	The wall of the tube is clear and transparent, the inner surface is smooth, and the promotion is convenient
Printing scale is clear and accurate	Printing scale is clear and accurate
Pressure rating: 300 kPa	Locking design improve the security and stability. Pressure rating: 300 kPa

The volume of two type control syringes that to be offered in 10ml, 12ml.

The sunmed™ Control Syringes are available with rotating male luer and fixed male luer. The rotating male luer can be rotated. When connected with the other device, they can rotate freely. While the fixed male luer cannot be rotated. The rotating male luer and fixed male luer both are in line with ISO 594-2:1998.

The sterilization method of the Sunmed™ Control Syringes is Ethylene Oxide sterilization.

5. Intended Use

The Sunmed™ Control Syringes is intended to inject contrast media or saline for angiographic procedures.

6. Technological Comparison to Predicate Device

The technological characteristics of the subject device, the Sunmed™ Control Syringes, are equivalent in intended use, materials, operating principle, sterility assurance level, and method of sterilization to the Medline Angiographic Control Syringes; and the Sunmed™ Control Syringes is also similar to the ANT Angiographic Syringes in that it consists of the intended use, operating principle, sterility assurance level, and method of sterilization.

7. Summary of Non-Clinical Testing

The following tests were performed; the results of the performance testing demonstrated the substantial equivalence of the Sunmed™ Control Syringes.

Biocompatibility Testing:
Acute Systemic Toxicity Test (two kinds of solvent)
Skin sensitization Test (two kinds of solvent)
In Vitro Hemolysis Study
Intracutaneous Reactivity Test (two kinds of solvent)
In Vitro Cytotoxicity Test

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™ Control Syringes is considered substantially equivalent to the Medline Angiographic Control Syringes and ANT Angiographic Syringes.