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 13, 2016

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

Re: K153685
Trade/Device Name: Sunmed Haemostatic Valves
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DTL
Dated: August 30, 2016
Received: September 13, 2016

Dear James 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,

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)*
K153685

Device Name
SunmedTM Haemostatic Valves

Indications for Use *(Describe)*

The SunmedTM Haemostatic Valves is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic and interventional devices up to an external diameter of 7 Fr, 8 Fr or 9 Fr; The insertion tool facilitates introduction of guide wire through the haemostatic valves to reach the guiding catheter; The torquer provides a handle for easier manipulation of the guide wire when inserted into the proximal end of the guide wire.

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."

5. 510(k) Summary

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: Aug.20, 2016

2. Proposed Device:

   Trade/Proprietary Name: Sunmed™Haemostatic Valves

   Common/Usual Name: Haemostatic Valves

   Classification: II

   Classification Name: Catheter guide wire

   Regulation Number: 870.1330

   Product Code: DQX

   Additional Product Code:

   Classification Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold or Fitting

   Regulation Number: 870.4290

   Product Code: DTL

3. Predicate Device:

510(k) Number	Trade Name	Manufacture	Note
K113148	E-Pass™	Synexmed (Shenzhen) company limited.	Primary predicate

K131124	CoLign™ Hemostasis Valve	Jilin Coronado Medical Ltd.	Reference devices
K073260	The LiiSA Lever Integrated Interventional System Adaptor™	Device Partners International	
K052381	The Guardian Hemostatic Valve	Zerusa Limited	
K133795	Sunmed™ Inflation Device	Sunny Medical Device (Shenzhen) Co., Ltd.	

4. Device description

Hemostatic valves is composed of single Y connector, insertion tool and torquer. There are four models of the Hemostatic valves: Push-pull Y Connector, Screw Y Connector, Y click Connector and Double Screw Y Connector.

Each single Y connector has two different structures: one is that the end of sideon is female luer; Another is that the end of sideon is the tubing and a stopcock.

The Sunmed™ Hemostatic Valvesis designed to three external diameter of 7F, 8F, 9F for through different specifications of guide wire or catheter according to clinical need.

5. Intended Use

The Sunmed™ Haemostatic Valves is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic and interventional devices up to an external diameter of 7F, 8F or 9F; The insertion tool facilitates introduction of guide wire through the haemostatic valves to reach the guiding catheter; The torque provides a handle for easier manipulation of the guide wire when inserted into the proximal end of the guide wire.

6. Technological Comparison to Predicate Device

The technological characteristics of the subject device, The Sunmed™ Haemostatic Valves, is equivalent to the E-Pass™ in terms of intended use, materials, fundamental scientific technology, operating principle, sterility assurance level, and method of sterilization.

7. Summary of Non-Clinical Testing

The following tests were performed on the Sunmed™Haemostatic Valves:

Biocompatibility Testing:
Pyrogen Test
Acute Systemic Toxicity Test(two kinds of solvent)
Skin sensitization Test (two kinds of solvent)

Endotoxin Test
In Vitro Hemolysis Study
Complement Activity Test (C3a,SC5b-9)
Intracutaneous Reactivity Test (two kinds of solvent)
In Vitro Cytotoxicity Test
Thrombosis Test
Package Penetrate Testing
Asepsis Testing
Aging Testing
EtO and ECH Residue Testing
Bench Testing

Conclusion: Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate devices. The safety and effectiveness of the Sunmed™ Haemostatic Valves has been demonstrated through data collected from nonclinical bench tests and analysis. Please refer to the Predicate Device Discussion Table for detail.

8. Clinical Evaluation was not applicable.

9. Conclusions

Based on the information presented in this 510(k) premarket notification, the Sunmed™ Haemostatic Valves is considered substantially equivalent to the E-Pass™ and CoLign™ Hemostasis Valve.