March 16, 2020

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

Re: K191827
Trade/Device Name: Sunmed™ Disposable Angio-Closure Pads
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: July 8, 2019
Received: July 8, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel Neubrander, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K191827

Device Name
Sunmed disposable angio-closure pads

Indications for Use *(Describe)*
The Sunmed disposable angio-closure pads is to assist in obtaining and maintaining hemostasis.

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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"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.

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Contact: JamesQi Zhang, General Manager

E-mail: jamesqizhang@gmail.com

Date: Mar 7, 2020

2. Proposed Device:

Trade/Proprietary Name: Sunmed™ disposable angio-closure pads

Common/Usual Name: disposable angio-closure pads

Classification: II

ClassificationName: Clamp, Vascular

Regulation Number: 870.4450

Product Code: DXC

3. Predicate Device:

510(k) Number	Trade Name	Manufacture
K062569	Safeguard™ 24cm pressure assisted dressing	Datascope Corp.

4. Device description

   The disposable angio-closure pads is composed of compression bulb, compression band and infusion mouth. Compression bulb is made from medical Polyurethane. Compression band is made from medical adhesive tape. Infusion mouth is made from medical Polycarbonate.

5. Intended Use

   The Sunmed™ disposable angio-closure pads is to assist in obtaining and maintaining hemnostasis.

6. Technological Comparison to Predicate Device

   The technological characteristics of the subject device, The Sunmed™ disposable angio-closure pads, are equivalent to the Safeguard™ 24cm pressure assisted dressing in terms of intended use, 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™ angio-closure pads:

   Biocompatibility Testing:
   Pyrogen Test
   Acute Systemic Toxicity Test(two kinds of solvent)
   Skin sensitization Test (two kinds of solvent)
   Intracutaneous Reactivity Test (two kinds of solvent)
   In Vitro Cytotoxicity Test
   Bacterial endotoxins 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™ disposable angio-closure pads is considered substantially equivalent to the Safeguard™ 24cm pressure assisted dressing.