August 5, 2020

Omay(Guangzhou)Med Technologies Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, NanShan Medical Devices Industrial Park
Nanshan District
Shenzhen, 518067 Cn

Re: K191955
Trade/Device Name: Enhanced External Counter Pulsation Device Plus Omay-A
Regulation Number: 21 CFR 870.5225
Regulation Name: External counter-pulsating device
Regulatory Class: Class II
Product Code: DRN
Dated: July 6, 2020
Received: July 6, 2020

Dear Kevin Wang:

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,

for Fernando Aguel
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)*
K191955

Device Name

Enhanced External Counter Pulsation Device Plus Omay-A

Indications for Use *(Describe)*
The OM-A device is intended for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. In addition, it is intended for use in healthy patients to provide improvement in vasodilation, and increased blood flow. It is intended for use under the oversight of a healthcare professional.

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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2019/11/05

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Enhanced External Counter Pulsation Device Plus Omay-A
Model	OM-A
Common Name	External Counter-Pulsation Device
Regulatory Class	Class II
Classification	870.5225 / Device, Counter-Pulsating, External / DRN
Submission type	Traditional 510(K)

4. Predicate Device

1) Primary Predicate Device Sponsor: Chongqing Psk Sci-tech Development Co., Ltd.
Trade/Device Name: External Counterpulsation Device with SPO2 Monitoring
Model: P-ECP/TI
510(k) #: K130439

2) Reference Device Sponsor: Vamed Medical Instrument Co., Ltd.
Device Name: External Counterpulsation System
Model: ECP-MC3
510(k) #: K190683

5. Device Description

Enhanced External Counterpulsation Device Plus OM-A is a computer-controlled system that applies external pressure via cuffs to the patient's lower extremities in synchronization with the patient's cardiac cycle. When the heart is in its relaxed state (diastole), pressure is applied sequentially; distal to proximal, from the lower legs (calves) to the lower thighs and then the upper thighs and buttocks, to propel blood back to the heart. The consequence is an increase in arterial blood pressure during diastole (diastolic augmentation) resulting in increased coronary perfusion pressure and coronary blood flow. Compression of the extremities also results in an increase in venous return to the heart. Just before the heart ejects blood (systole), air is released rapidly from all the cuffs simultaneously to release the externally applied pressure, allowing the compressed vessels to recover to their normal shape, thereby reducing vascular impedance. As a result, arterial pressure during systole is reduced (systolic unloading), as is cardiac workload. The patient's calves, lower thighs, upper thighs and buttocks are wrapped with cuffs containing air bladders. The patient's ECG is monitored via conventional, high-quality electrodes and detection of the R-wave is used to signal the System when to command sequential inflation of the cuffs. The start and duration of inflation, as well as the start of deflation, are adjustable by the Operator, within limits determined by the System. An algorithm is used to prevent the start of inflation during ejection of blood from the heart and to end inflation and begin deflation prior to the occurrence of the next heartbeat. The pressure applied by the cuffs is also adjustable by the Operator from 150mmHg to 300mmHg (for a patient with a heart rate of 60 bpm).
The device also utilizes the following cleared components:
ECG/EKG and SpO2: K123711

6. Intended use & Indication for use

The OM-A device is intended for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. In addition, it is intended for use in healthy patients to provide improvement in vasodilation, and increased blood flow. It is intended for use under the oversight of a healthcare professional.

7. Comparison to the Predicate Device

Comparison to Primary Predicate Device under K130436

Features	**Subject Device OM-A**	**Primary Predicate Device K130439 P-ECP/TI**	**Conclusion**
Applicant	Omay (Guangzhou) Med Technologies Co., Ltd.	Chongqing PSK Sci-tech Development Co., Ltd.	/
Classificatio n Regulation	21CRF 870.5225	21CRF 870.5225	Same
Product Code	DRN	DRN	Same
Common name	Counter-Pulsating, External	Counter-Pulsating, External	Same
Triggering Mechanism	R-Wave trigger	R-Wave trigger	Same

Features	Subject Device OM-A	Primary Predicate Device K130439 P-ECP/TI	Conclusion
Microprocessor	Windows Based	Windows Based	Same
Emergency System power-down	Red	Red	Same
Pressure setting	Setting range: 5mmHg to 350mmHg Setting step: 1mmHg Error: ± 10mmHg	Setting range: 1kPa~50kPa Setting step: 1kPa Error: ± 2kPa	Different (1)
Treatment time	Setting range: 1min~45min	Setting range: 1min~60min	Different (2)
Cuff system	Three parts, calf, thigh and buttocks.	Three parts, calf, thigh and buttocks.	Same
Dimension/ Weight	2000mm × 800mm × 700mm, 180kg	2070mm × 1120mm × 1100mm, 220kg	Different (3)
Major components	Base Unit, Air-Tubes, ECG SPO2 and three Cuffs	Base Unit, Air-Tubes, ECG SPO2 and three Cuffs	Same
Operating Environment	10°C ~30°C; Relative humidity: less than 85%; Atmospheric pressure: 70kPa~106kPa	10°C ~30°C; Relative humidity: less than 85%; Atmospheric pressure: 70kPa~106kPa	Same
Safety and EMC	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Justifications for differences between proposed device and the primary predicate device are shown as below:

Different (1) Pressure setting: The subject device's range of pressure is within predicate device. The error is less than predicate device. Thus, this difference will not cause any safety and effectiveness issues.
Different (2) Treatment time: The subject device's range of treatment time is within predicate device. Thus, this difference will not cause any safety and effectiveness issues.
Different (3) Dimension/Weight: This feature is not related to clinical use and it is only a design consideration. Thus, this difference will not cause any safety and effectiveness issues.

Comparison to Reference Device under K190683

Features	Subject Device OM-A	Reference Device K190683 ECP-MC3	Conclusion
Applicant	Omay (Guangzhou) Med	Vamed Medical Instrument Co.,	/

Features	Subject Device OM-A	Reference Device K190683 ECP-MC3	Conclusion
	Technologies Co., Ltd.	Ltd.	
Classification Regulation	21CRF 870.5225	21CRF 870.5225	Same
Product Code	DRN	DRN	Same
Common name	Counter-Pulsating, External	Counter-Pulsating, External	Same
Indication for use	The OM-A device is intended for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. In addition, it is intended for use in healthy patients to provide improvement in vasodilation, and increased blood flow. It is intended for use under the oversight of a healthcare professional.	The ECP-MC3 device is intended for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. In addition, it is intended for use in healthy patients to provide improvement in vasodilation, and increased blood flow. It is intended for use under the oversight of a healthcare professional.	Same

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the OM-A was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The subject devices are considered surface contacting for a duration of exceed 24 hours but not 30 days.

Non-clinical data

The OM-A Enhanced External Counter Pulsation Device Plus Omay-A have been tested according to the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment-

Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests

The test was selected to show substantial equivalence between the subject device and the predicate.

Clinical data

Clinical data were not required in this submission to support a finding of substantial equivalence.

9. Conclusion

We conclude that the information provided in this submission is sufficient to demonstrate that the OM-A Enhanced External Counter Pulsation Device is substantially equivalent to the predicate device which is currently marketed for the same intended use.