September 10, 2019

Vamed Medical Instrument Co., Ltd
℅ Jet Li
Regulation Manager
Guangzhou KEDA Testing Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, 510060 Cn

Re: K190683
Trade/Device Name: External Counter Pulsation System; Model ECP-MC3
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: Class II
Product Code: DRN
Dated: September 1, 2019
Received: September 5, 2019

Dear Jet Li:

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,

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)*
K190683

Device Name
External Counterpulsation System; Model ECP-MC3

Indications for Use *(Describe)*
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.

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 870.5225, and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: Vamed Medical Instrument Co., Ltd

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Application Correspondent: Jet Li

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Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

2. Subject Device Information

Type of 510(k) submission:	Traditional
Common Name:	External Counterpulsation System
Model:	ECP-MC3
Classification Name:	External counter-pulsating device
Review Panel:	Cardiovascular
Product Code:	DRN
Regulation Number:	21 CFR 870.5225

Regulation Class: 2

3. Predicate Device Information

1) Primary Predicate Device
Sponsor: Chongqing Psk Sci-tech Devolpment Co., Ltd.

510K number: K130439

Trade/Device Name: External Counterpulsation Device with SPO2 Monitoring

Model: P-ECP/TI

Regulation Number: 21 CFR 870.5225

Repletion Name: External Counter-Pulsating Device

Regulatory Class: Class II

Product Code: DRN

2) Secondary Predicate Device
Sponsor: Xtreem Pulse, LLC

Device Name: External Counter-Pulsation Device

Model: PureFlow

Classification Name: External counter-pulsating device

510(k) number: K173483

Review Panel: Cardiovascular

Product Code: DRN

Regulation Number: 21 CFR 870.5225

4. Device Description

ECP-MC3 is the most updated designed External Counter Pulsation System for non-invasive treatment of certain cardiovascular and other ischemia related diseases.
The ECP-MC3 system is computer-controlled system that inflates and deflates three pairs of air cuffs in synchronization with the patient's cardiac cycle. The three pairs of cuffs are wrapped around the calves, lower thighs, and upper thighs/buttocks of the patients. As diastole begins, the cuffs inflate separately in sequence from the calves, to the lower thighs, to the upper thighs including the lower buttocks. This inflation sequence generates and impels a counter-pulsation wave, increasing diastolic blood pressure (diastolic augmentation), coronary perfusion pressure and coronary blood flow, and

raising cardiac output.

The start of inflation, deflation and cuff pressure can be adjusted by the operator. The system will deflate simultaneously before systole, this will reduce the heart's workload and resistance of blood vessel.

Before ECP treatment, ECG electrodes and Finger Clip plethysmograph Sensor are placed on the patient. The ECG waveform is used to generate triggering signals for cuff inflation and deflation. The plethysmograph waveform is used to monitor the proper timing of the inflation/deflation cycle and to indicate the effect of ECP treatment on patient homodynamic.

5. Intended Use

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.

6. Non clinical testing:

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

- **Reliability test :**

The device was evaluated for reliability for lifetime of three years, based on information provided by the manufacturer estimated use conditions according to CFR21 sec. 870.5225.

- **Performance Testing before and after reliability test**

Performance of subject device was evaluated according to CFR21 sec. 870.5225 for below testing item:

Pressure Control Timing Testing

The device was evaluated for synchronization of therapy with the appropriate phase of cardiac cycle or functionality of alarms per the special control in 21 CFR 870.5225. The Trigger Mechanism (R- wave trigger), Trigger range and External trigger ratio were tested and met the acceptance criteria (comparing to predicate device).

Pressure Range Accuracy Testing

Pressure was set for each device, and the actual pressure was measured to check if accuracy is verified.

Referenced standard used was GB 10035-2017 Air-bag type sequential external counter-pulsation device. The measurement Pressure difference was less than +/- 10% from the set pressure value.

- ***Electrical safety and electromagnetic compatibility (EMC)***

Electrical safety and EMC testing were conducted on the subject device, and was found to comply with IEC 60601-1 and 60601-1-2.

And the device was also evaluated to comply with IEC60601-1-6 for General Requirements For Usability; and IEC60601-1-8 General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems

Detail standard lists is as below items:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005+A1:2012
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2014
- IEC 60601-1-6 Edition 3.1 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 60601-1-8: 2006 (Second Edition) + Am.1: 2012 Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems

- **Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was determined to be of "moderate" level of concern.

7. Clinical Testing

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

8. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended

use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device（Primary）**	**Predicate Device (Secondary)**	**Verdict**
Manufacturer	Vamed Medical Instrument Co., Ltd	Chongqing Psk Sci-tech Devolpment Co., Ltd	Xtreem Pulse, LLC	--
K number	K190683	K130439	K173483	
Product Name	External Counterpulsation System ECP-MC3	External Counterpulsation Device P-ECP/TI	External Counter-Pulsation Device PureFlow	--
Classification Name	External counter-pulsating device	External counter-pulsating device	External counter-pulsating device	
Regulation Class	2	2	2	
Regulation Number	21 CFR 870.5225	21 CFR 870.5225	21 CFR 870.5225	
Indications for Use				
Indications for Use	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.	The intended use of the ECP device is to provide external counterpulsation (ECP) therapy, and is indicated for use in the treatment of stable or unstable angina pectoris, congestive heart failure, cardiogenic shock and acute myocardial infarction.	The Pure Flow External Counter-Pulsation 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, increased VO2, and increased blood flow. It is intended for use under the	SE Note 1

Elementsof Comparison	**Subject Device**	**Predicate Device （Primary）**	**Predicate Device(Secondary)**	**Verdict**
			oversight of a healthcare professional.	
Device Design				
Triggering Mechanism	R-Wave trigger for inflation	R-Wave trigger for inflation	T-Wave trigger for inflation and P-Wave deflation timing	SE
Microprocessor	Windows Based	Windows Based	Windows Based	SE
Emergency System power-down	Patient Emergency Stop Button	Patient Emergency Stop Button	Red-Emergency Stop Button	SE
Maximum pressure used for treatment/timer settings	50kPa 0 to 120min, defaulted as 60min	0-350mmHg 0 to 60min	4.0 psi(=27.58kPa) Timer: 1-60 minutes (Single minute increments)	SE
Counterpulsation Duty	1:1 or 1:2 to choose	1:1 or 1:2	1:1 or 1:2	SE
Cuff system	the Calf Cuff, the Lower Thigh Cuff and the Upper Cuff	the Calf Cuff, the Lower Thigh Cuff and the Upper Cuff	Nylon fabric cuffs, three parts, calf, thigh and buttocks.	SE
Major components	Counterpulsation Bed, Cuff kits, ECG Cable, Integrated Finger Sensor	Counterpulsation Bed, Cuff kits, ECG Cable, Integrated Finger Sensor , SPO2	Base Unit, Air-Tubes, EKC, SPO2, EKG and three Cuffs	SE Note 2
Voltage/Hz/Wattage	AC 120V 60Hz	AC 120V 60Hz	100-240V 50/60HZ	SE Note 3
Dimension/Weight	2160×810×650(mm) 255kg	2070mmX1120mmX1100mm 204KG	1250mmX700mmX500mm 120KG	SE Note 3
Operating Environment	Temperature: 10~30℃ Relative Humidity: ≤80% Atmospheric Pressure: 86kPa~106kPa	Temperature: 10~30℃ Relative Humidity: ≤80%	Temperature: 10℃ to 30℃ (50℉- 86℉) Humidity: 30% to	SE Note 3

Elementsof Comparison	**Subject Device**	**Predicate Device （Primary）**	**Predicate Device(Secondary)**	**Verdict**
		Atmospheric Pressure: 86kPa~106kPa	75% RH (non-condensing) Barometric Pressure: 80kPA to 100kPA	
FDA-Recognized Standards				
Electrical safety, EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6	SE

Note 1

Although there is little difference for illustration about the indication for use, the description of the predicate device is more specified, yet their meanings are the same. This difference does not affect the safety and effectiveness.

Note 2

Although the subject device does not provide with SPO2, since it is not provided with the function for monitoring SPO2; but the treatment is supervised by the qualified physician, so for the subject device's intended use, SPO2 is not mandatory and it will not affect the safety and effectiveness.

Note 3

Although the device design and part of functional parameters between the predicate device and subject device are different, they are both complied with IEC 60601-1. So the minor differences on such parameters do not affect the safety and effectiveness.

9. Summary for clinical test

Clinical performance is not deemed necessary.

10. Conclusion

The subject device External Counterpulsation System has all features of the predicate device for intended use.
Through the reliability testing, it demonstrate that the subject device is as effective and performs as well as the predicate device in its lifetime; And through the performance testing, the device was tested and demonstrated for its synchronization of therapy and pressure control accuracy.

The non- clinical tests demonstrate that subject device is as safe, as effective, and performs as well as the predicate device(s). Thus, the subject device is substantially equivalent to the predicate device.

11. Summary Prepared Date

17 July. 2019