August 28, 2020

Vamed Medical Instrument Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou Keda Biological Tech Co., Ltd.
6F, No. 1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong 510060
China

Re: K202108
Trade/Device Name: External Counterpulsation System, Soulaire
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: Class II
Product Code: DRN
Dated: July 27, 2020
Received: July 30, 2020

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,

for Fernando Aguel
Assistant Director
Division of Circulatory Support,
Structural and Vascular Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

1 Submitter Information

Sponsor: Vamed Medical Instrument Co., Ltd.
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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: Special 510(k): Device Modification
Common Name: External Counterpulsation System , Soulaire
Classification Name: External counter-pulsating device
Review Panel: Cardiovascular
Product Code: DRN
Regulation Number: 21 CFR 870.5225
Regulation Class: 2

3 Legally marketed device (predicate device) Information

Common Name: External Counterpulsation System
Model: ECP-MC3
510(K) Number: K190683
Classification Name: External counter-pulsating device
Review Panel: Cardiovascular
Product Code: DRN
Regulation Number: 21 CFR 870.5225
Regulation Class: 2

4 Device Description

The External Counterpulsation System, Soulaire device has similar design to the External

Counterpulsation System Model ECP-MC3.

The Soulaire 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 Indication for Use

The External Counterpulsation System, Soulaire 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.

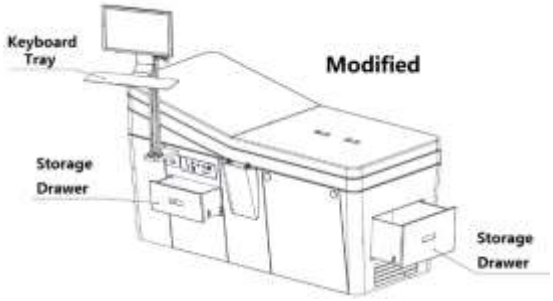
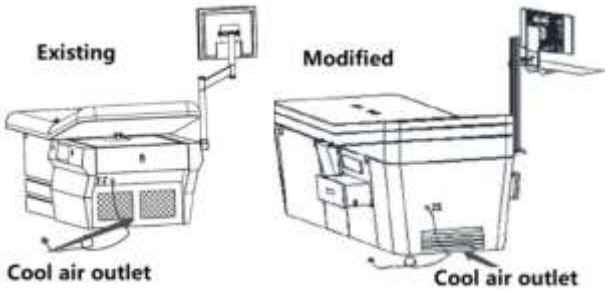
6 Complied Standards

External Counterpulsation System, Soulaire complies with the following FDA recognized consensus standards:

- ☒ ANSI/AAMI ES60601-1:2005 + A1:2012, C1:2009 and A2:2010 Medical Electrical Equipment - Part 1: General Requirements for Safety
- ☒ 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
- ☒ Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

7 Device modification description

All the modifications of subject device are shown in the following table as below, and no other changes were made to legally existing predicate device.

<table>
<tr><th>Item</th><th>Design modification</th><th>Before modification (K190683)</th><th>After modification</th></tr>
<tr><td>Labeling</td><td>Model name</td><td>ECP-MC3</td><td>Soulaire</td></tr>
<tr><td>Software</td><td>Company logo</td><td></td><td></td></tr>
<tr><td rowspan="4">Device design</td><td>Add 3 storage drawers</td><td colspan="2" rowspan="2"> 
</td></tr>
<tr><td>Add keyboard tray</td></tr>
<tr><td>Integrated Cool air outlet</td><td colspan="2"> 
</td></tr>
<tr><td>Dimensions</td><td>2160×810×650(mm)</td><td>2240×940×970(mm)</td></tr>
<tr><td>Weight</td><td>255kg</td><td>300kg</td></tr>
</table>

8 Performance Testing

As the modifications of subject device as below, results in no technological characteristics changes, the tests and data utilized to demonstrate the substantial equivalence of the predicate devices are suitable for use in the assessment of the subject devices.

As there have been no changes to the performance of the subject devices from the predicate devices, this submission leverages performance and electrical testing provided in previous submissions.

9 Biocompatibility

All the modified device materials which come in direct contact with the patient skin are biocompatible and identical to the materials used in the predicate device manufacturing. No biocompatibility test report is provided in this submission.

10 Clinical performance

Clinical performance is not deemed necessary.

11 Comparison with predicate device

Compare with predicate device (External Counterpulsation System ECP-MC3 (K190683)), the subject device (External Counterpulsation System, Soulaire) is very similar in design principle, intended 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.

Item	Subject Device	Predicate Device	Verdict
Manufacturer	Vamed Medical Instrument Co., Ltd	Vamed Medical Instrument Co., Ltd	--
K number	TBD	K190683	--
Product Name	External Counterpulsation System, Soulaire	External Counterpulsation System ECP-MC3	--
Regulation & Classification	External counter-pulsating device DRN Class 2 21 CFR 870.5225	External counter-pulsating device DRN Class 2 21 CFR 870.5225	Same
Indications for Use	The External Counterpulsation System, Soulaire 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.	SE
Device design			
Triggering Mechanism	R-Wave trigger for inflation	R-Wave trigger for inflation	Same
Microprocessor	Windows Based	Windows Based	Same
Emergency System power-down	Patient Emergency Stop Button	Patient Emergency Stop Button	Same
Maximum pressure used for treatment/timer settings	50kPa 0 to 120min, defaulted as 60min	50kPa 0 to 120min, defaulted as 60min	Same
Counterpulsation Duty	1:1 or 1:2 to choose	1:1 or 1:2 to choose	Same
Cuff system	the Calf Cuff, the Lower Thigh Cuff and the Upper Cuff	the Calf Cuff, the Lower Thigh Cuff and the Upper Cuff	Same
Major components	Counterpulsation Bed, Cuff kits, ECG	Counterpulsation Bed, Cuff kits, ECG	Same

	Cable, Integrated Finger Sensor	Cable, Integrated Finger Sensor	
Voltage/Hz/Wattage	AC 120V 60Hz	AC 120V 60Hz	Same
Dimension Weight	2240×940×970(mm) 300kg	2160×810×650(mm) 255kg	SE Note 1
Operating Environment	Temperature: 10~30℃ Relative Humidity: ≤70% Atmospheric Pressure: 86kPa~106kPa	Temperature: 10~30℃ Relative Humidity: ≤70% Atmospheric Pressure: 86kPa~106kPa	Same
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 60601-1-6, IEC 60601-1-8	Same

Note 1

Although the dimension and weight of subject device are little difference to the legally existing predicate device, the modification of subject device is only about the external structure and company logo in software, not involved with technical specifications, so the difference does not affect the substantial equivalence.

Conclusion

The subject device (External Counterpulsation System, Soulaire) has all features of the predicate device for intended use. Thus, the subject device is as safe and effective as the predicate device.

12 Summary Prepared Date:

05 May. 2020