



December 22, 2025

Pression, Inc.
% Julie Broderick
Principal Consultant
Broderick Regulatory Consulting, LLC
7 Kendall Street
Winchester, Massachusetts 01890

Re: K250756

Trade/Device Name: Pression Wave PRO External Counter-Pulsation System
Regulation Number: 21 CFR 870.5225
Regulation Name: External counter-pulsating device
Regulatory Class: Class II
Product Code: DRN
Dated: October 10, 2025
Received: October 14, 2025

Dear Julie Broderick:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nicole M. Gillette -S

Nicole Gillette

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K250756

?

Please provide the device trade name(s).

?

Pression Wave™ PRO External Counter-Pulsation System

Please provide your Indications for Use below.

?

The Pression Wave PRO External Counter-Pulsation System is indicated for the treatment of chronic stable angina (CSA) that is refractory to optimal anti-anginal medical therapy and without options for revascularization in adult patients that weigh greater than 40kg. In addition, it is intended for use in healthy adult patients to provide improvement in vasodilation, increased VO₂, and increased blood flow. It is intended for use under the supervision of a healthcare professional.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter Information

Company: Pression, Inc.
190 West Lincoln Highway
Coatesville, PA 19320 USA

Contact: Adam Salamon
President & CEO
Pression, Inc.
Phone No.: +1 215-326-9525
Email: adam@pression.com

Date Prepared: 22 December 2025

510(k) No.: K250756

II. Name of Device

Device Trade Name: Pression Wave™ PRO External Counter-Pulsation System
Model No.: WP-01
Classification Name: Device, Counter-Pulsating, External
Product Code: DRN
Regulation Number: 21 CFR 870.5225, External counter-pulsating device
Device Class: II
Panel Identification: Cardiovascular

III. Predicate Devices

All predicate and reference devices listed below are in the same Product Code:

Classification Name: Device, Counter-Pulsating, External
Product Code: DRN
Regulation Number: 21 CFR 870.5225, External counter-pulsating device
Device Class: II
Panel Identification: Cardiovascular

Predicate Device

Manufacturer: Applied Cardiac Systems, Inc. (ACS)
Trade Name: ACS Model NCP-2 External Counterpulsation System
510(k) No.: K042413

Reference Devices

Manufacturer:	Vamed Medical Instrument Co., Ltd
Trade Name:	External Counterpulsation System, ECP MC-3
510(k) No.:	K190683
Manufacturer:	CardioMedics, Inc.
Trade Name:	CardiAssist Counterpulsation System, Mark 3000
510(k) No.:	K022107
Manufacturer:	Renew Group Pte Ltd. / Stage 2 Innovations
Trade Name:	Renew NCP-5 External Counterpulsation System
510(k) No.:	K152115

IV. Device Description

External counter-pulsation (ECP) as a general technology involves the application of pressure to the patient's legs using inflatable cuffs or sleeves to enhance perfusion at the heart. ECP using the Wave PRO involves wrapping the patient's calves in sleeves containing inflatable bladders, which compress the calves in sync with the patient's cardiac cycle. During diastole, a series of five bladders within the sleeves inflate sequentially from the patient's ankles towards their knees. This compression results in diastolic augmentation, which is observable from the pulse data obtained using a finger-tip PPG sensor. During the diastolic phase, the heart is relaxed, allowing for coronary perfusion to the cardiac muscle. By compressing the inflatable bladders during this portion of the cardiac cycle, aortic retrograde flow is increased, allowing for enhanced coronary perfusion.

The Pression Wave PRO System consists of three primary subsystems: 1) the Compression Control System, which controls the flow of compressed air to the sleeves, measures the phase of the cardiac cycle, and provides the graphical user interface (GUI); 2) Patient-Worn Calf Sleeves, which direct the compressive force of compressed air, delivered comfortably and consistently, to the patient's calf muscles; and 3) the Compression Timing Algorithm (Software), which determines when the patient's heart is in diastole, using a photoplethysmography (PPG) sensor, and controls the timed application of compression to the patient's calf muscles..

V. Indications for Use

The Pression Wave PRO External Counter-Pulsation System is indicated for the treatment of chronic stable angina (CSA) that is refractory to optimal anti-anginal medical therapy and without options for revascularization in adult patients that weigh greater than 40kg. In addition, it is intended for use in healthy adult patients to provide improvement in vasodilation, increased VO₂, and increased blood flow. It is intended for use under the supervision of a healthcare professional.

VI. Comparison of Technological Characteristics

Characteristic	<u>New Device</u> <i>Wave PRO External Counter-Pulsation System</i>	<u>Predicate Device</u> <i>Model NCP-2 External Counterpulsation System</i>	<u>Reference Device</u> <i>Model ECP-MC3 External Counterpulsation System</i>	<u>Reference Device</u> <i>CardiAssist Counterpulsation System, Mark 3000</i>	<u>Reference Device</u> <i>Renew NCP-5 External Counterpulsation System</i>	Substantial Equivalence
Manufacturer	Pression, Inc.	Applied Cardiac Systems, Inc.	Vamed Medical Instrument Co., Ltd.	CardioMedics, Inc.	Renew Group Pte Ltd. / Stage 2 Innovations, Inc.	N/A
510(k) Number	K250756	K042413	K190683	K022107	K152115	N/A
Regulation No.	21 CFR 870.5225	21 CFR 870.5225	21 CFR 870.5225	21 CFR 870.5225	21 CFR 870.5225	Substantially Equivalent Same as predicates
Regulation Name	External counter-pulsating device	External counter-pulsating device	External counter-pulsating device	External counter-pulsating device	External counter-pulsating device	Substantially Equivalent Same as predicates
Regulatory Class	Class II	Class II	Class II	Class II	Class II	Substantially Equivalent Same as predicates
Product Classification Code	DRN	DRN	DRN	DRN	DRN	Substantially Equivalent Same as predicates
Intended Use / Indications for Use	The Pression Wave PRO External Counter-Pulsation System is indicated for the treatment of chronic stable angina (CSA) that is refractory to optimal anti-anginal medical therapy and without options for revascularization in adult patients that weigh greater than 40 kg. In addition, it is intended for use in healthy adult patients to provide improvement in	ACS Model NCP-2 External Counterpulsation Device is a noninvasive external Counterpulsation device intended for the use in the treatment of patients with stable or unstable angina pectoris, acute myocardial infarction, cardiogenic shock or congestive heart failure.	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 improvements in vasodilation, and increased blood flow. It is intended for use under the	The CardioMedics, Inc., CardiAssist Counterpulsation System, Mark 3000, is intended to provide external counterpulsation (ECP) for the treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction and cardiogenic shock. Use of this	The Renew NCP-5 External Counterpulsation System 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	Substantially Equivalent Substantially the same as predicates ¹ .

¹ The ACS Model NCP-2 External Counterpulsation System and CardiAssist Counterpulsation System Mark 3000 were cleared prior to FDA's reclassification of ECP systems for indications other than chronic stable angina to class III (PMA) in December 2013. Both device indication/intended use includes chronic or stable angina pectoris within the cleared indication, which is the same as the Pression Wave device (chronic stable angina).

Characteristic	<u>New Device</u> <i>Wave PRO External Counter-Pulsation System</i>	<u>Predicate Device</u> <i>Model NCP-2 External Counterpulsation System</i>	<u>Reference Device</u> <i>Model ECP-MC3 External Counterpulsation System</i>	<u>Reference Device</u> <i>CardiAssist Counterpulsation System, Mark 3000</i>	<u>Reference Device</u> <i>Renew NCP-5 External Counterpulsation System</i>	Substantial Equivalence
	<p>vasodilation, increased VO₂, and increased blood flow.</p> <p>It is intended for use under the supervision of a healthcare professional.</p>		<p>oversight of a healthcare professional.</p>	<p>device may reduce pain and impairment associated with angina pectoris, congestive heart failure or myocardial infarction and may enhance coronary function.</p>	<p>under the oversight of a healthcare professional.</p>	
<p>Device Description / Operating Principle</p>	<p>The application of pressure to the patient’s legs using inflatable cuffs or sleeves surrounding the calves, inflated sequentially from the ankle to the knee and synchronized to the diastolic phase of the cardiac cycle, results in diastolic augmentation and systolic unloading, which is observable from the pulse data obtained using a finger-tip PPG sensor. During the diastolic phase, the heart is relaxed, allowing for coronary perfusion to the cardiac muscle. By compressing the inflatable sleeves during this portion of the cardiac cycle, aortic retrograde flow is increased, allowing for enhanced coronary perfusion and systolic unloading.</p>	<p>When the heart is in its relaxed state during the diastolic period, pressure is applied sequentially from the calves, to the lower thighs, to the upper thighs and buttocks, forcing blood back to the heart, increasing coronary perfusion pressure and coronary blood flow (diastolic augmentation), as well as venous return. Immediately before the heart begins to eject blood during the next systolic phase, the <i>Cuffs</i> are rapidly deflated and all externally applied pressure is eliminated. The vasculature in the lower extremities re-conforms and is able to receive the output of the heart with lessened resistance, thereby reducing systolic pressure and the workload of the heart (decreased after-load).</p> <p>Although not specifically mentioned in the predicate 510(k) summary, systolic unloading is a known hemodynamic effect of ECP.</p>	<p>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.</p> <p>Although not specifically mentioned in the predicate 510(k) summary, systolic unloading is a known hemodynamic effect of ECP</p>	<p>The CardioMedics CardiAssist ECP System is a non-invasive circulatory assist device which provides increased circulation via external counterpulsation (ECP) for the treatment of ischemic heart disease including congestive heart failure, chronic angina pectoris, acute myocardial infarction and cardiogenic shock. External counterpulsation therapy improves cardiac function by enhancing the perfusion of the coronary vasculature, the development of coronary collateral circulation, and by reducing the workload of the heart.</p> <p>The CardiAssist ECP System consists of the portable console containing the computer and pumps with a touch screen for user interface, an integral strip chart recorder, and leg cuffs and hoses. Additional components provided with the System include a finger plethysmograph and 3-lead ECG cable and leads.</p> <p>This CardiAssist ECP System sequentially compresses the legs from the calves, thighs and</p>	<p>The Renew™ NCP-5 External Counterpulsation System (ECS) is comprised of the following major components, a switch panel, laptop PC computer, a foldable treatment bed, main unit, and a set of patient cuffs. The device is a microprocessor-controlled system that sequentially inflates then deflates three pairs of air cuffs, which compress vascular beds in the muscles of the calves, thighs, and buttocks in synchrony with the heart cycle to achieve the desired therapy.</p>	<p>Substantially Equivalent</p> <p>Same as predicates except that the Wave PRO utilizes sleeves on the calves only, whereas the predicate devices utilize cuffs on the calves, thighs and buttocks/hips. Clinical data included in the 510(k) demonstrate that the Wave PRO System produces the same or better hemodynamic effect as the predicate device.</p> <p>The Wave PRO is portable and substantially equivalent in this feature to the CardiAssist and Renew ECP reference devices.</p>

Characteristic	<u>New Device</u> <i>Wave PRO External Counter-Pulsation System</i>	<u>Predicate Device</u> <i>Model NCP-2 External Counterpulsation System</i>	<u>Reference Device</u> <i>Model ECP-MC3 External Counterpulsation System</i>	<u>Reference Device</u> <i>CardiAssist Counterpulsation System, Mark 3000</i>	<u>Reference Device</u> <i>Renew NCP-5 External Counterpulsation System</i>	Substantial Equivalence
				<p>buttocks, 40 milliseconds apart, by inflating three sets of flexible fabric cuffs during diastole. This results in movement of blood from the legs to the heart and entire upper body. Pressure, up to 310 mmHg, is applied with the timing and duration of each pulse, synchronized with the patient's ECG. When properly triggered, the pressure pulses applied to the vascular bed of the legs and buttocks transmit retrograde pressure through the entire vascular system. At the aorta, the aortic valve prevents retrograde flow into the left ventricle. Thus, a peak pulse of diastolic pressure occurs at or above systolic levels which increases the driving pressure in the coronary vasculature</p>		
Portability	Portable (34 kg)	Stationary	Stationary	Portable (~400 kg)	Portable (~250 kg)	<p>Substantially Equivalent Same as portable reference devices but much lighter</p>
Treatment pressure range	41-50 kPa (6-7.25 PSI) (automatically set)	13-41 kPa (1.9-6 PSI) (manually set)	0-50 kPa (0-7.25 PSI) (manually set)	11-41 kPa (1.6-6 PSI) (manually set)	0-41 kPa (0-6 PSI) (manually set)	<p>Substantially Equivalent Same as ECP-MC3 reference predicate</p>
Maximum safety pressure	55.2 kPa (8 PSI)	55.2 kPa (8 PSI)	55 kPa (8 PSI)	Unreported	Unreported	<p>Substantially Equivalent Same as predicate and ECP-MC3 reference device</p>

Characteristic	<u>New Device</u> <i>Wave PRO External Counter-Pulsation System</i>	<u>Predicate Device</u> <i>Model NCP-2 External Counterpulsation System</i>	<u>Reference Device</u> <i>Model ECP-MC3 External Counterpulsation System</i>	<u>Reference Device</u> <i>CardiAssist Counterpulsation System, Mark 3000</i>	<u>Reference Device</u> <i>Renew NCP-5 External Counterpulsation System</i>	Substantial Equivalence
Software validation	Per FDA guidance, Content of Premarket Submissions for Device Software Functions, June 2023	Per FDA guidance, General Principles of Software Validation, January 2002	Per FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (version unknown)	Unknown	The software and firmware used in the system was validated per FDA’s guidance document. In all instances, the NCP-5 system functioned as intended.	Substantially Equivalent Same as predicate
Electrical safety	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Per IEC 601-1-4, Medical Electrical Equipment Part 1: General requirements for safety. Collateral Standard: Programmable electrical medical systems, 1996-05	IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005+A1:2012	Unknown	Electrical safety and EMC compatibility testing per IEC 60601 was performed to ensure appropriate electrical performance.	Substantially Equivalent Same as reference devices, using most recent standard
Electromagnetic compatibility (EMC)	IEC EN 60601-1-2, Edition 4.1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Unknown	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	Unknown	Electrical safety and EMC compatibility testing per IEC 60601 was performed to ensure appropriate electrical performance.	Substantially Equivalent Same as reference devices, using most recent standard
Usability	Per FDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices, February 2016	Unknown	IEC 60601-1-6 Edition 3.1 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	Unknown	Unknown	Similar Similar to reference predicate, using most recent FDA guidance; achieves same goal
Clinical testing	A clinical investigation of the Wave PRO has demonstrated substantial equivalence to the predicate device.	Yes, 510(k) summary states: An Independent Review Board has overseen the clinical investigation of the External Counterpulsation Device. Results have demonstrated substantial equivalence to the predicate device.	Clinical performance is not deemed necessary.	Unknown	A literature review regarding the use of external counterpulsation in healthy patients was provided to support this additional indication.	Substantially Equivalent Same as predicate

VII. Performance or Clinical Testing

Bench performance testing to verify the design of the Pression Wave PRO System, all of which PASSED, included:

- Compression and Sensor Accuracy
- Product Safety & Electrical Testing
- EMC Testing
- Software Verification
- End of Line / Performance Test
- Label Verification
- Cycle Verification
- Service Life Verification (system and compression sleeves)
- Reprocessing Validation (compression sleeves)
- Summative Usability Testing
- Biocompatibility Assessment

The following standards were applied:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62304, Software lifecycle processes
- ISO 10993-1, Biological evaluation of medical devices – Part 1: evaluation and testing within a risk management process
- ISO 14971, Medical devices — Application of risk management to medical devices
- ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

The WaveCRESST clinical study demonstrated that the Wave PRO ECP System is non-inferior to the predicate device, ACS Model NCP-02 ECP System, with respect to the primary effectiveness endpoint, diastolic augmentation (DA) ratio. Details of the study are as follows:

- **Level of Evidence:** Randomized crossover-control study comparing Wave PRO ECP to ACS Model NCP-02 ECP (sequence of device use was randomized).
- **Study Population:** Volunteer participants at least 35 years of age with a history of mild to moderate coronary artery disease, but otherwise healthy.
- **Location of Study:** United States (one site)
- **Safety Endpoints:** Rates of device-related adverse events and device-related serious adverse events

- Primary Effectiveness Endpoint:** DA ratio during the 8th minute of compressions, as calculated by the blinded Independent Waveform Evaluator. The difference of the average DA ratio attained using the Wave PRO and the predicate device was calculated for all randomized study participants with paired ECP data., with randomized assignment of ECP device sequence and unbiased (blinded) waveform scoring of primary effectiveness endpoint, DA ratio, and secondary endpoint systolic unloading.
- Patient Accountability:**

	Total	Randomization	
		Wave PRO First	ACS First
Screened	60		
Screen fail	8		
Randomized (Intent to Treat)	52	26	26
Modified Intent to Treat Cohort & Safety Cohort (mITT) (received any ECP compressions)	51	25	26
Completed Study	48	22	26
Per Protocol (PP) Cohort (received any compressions from both ECP treatments with no major protocol deviations)	48	22	26

- Baseline Demographic Information (mITT population, N=51):**
 - Sex (% female): 47.1%
 - Age at procedure (mean ± SD, range): 60.9 ± 9.1 (41.0, 78.0)
 - Race: 2% American Indian/Alaska Native; 2.0% Asian; 47.1% Black/African American; 45.1% White; 2.0% Other; 2.0% Unknown
 - Ethnicity (% Hispanic or Latino): 2.0%
 - BMI (kg/m²) (mean ± SD, range): 32.6 ± 6.8 (17.7, 50.5)
 - Fitzpatrick Skin Type: type I = 5.9%; type II = 19.6%; type III = 19.6%; type IV = 7.8%; type V = 33.3%; type VI = 13.7%
- Results, Primary Effectiveness Endpoint:** The WaveCRESST study met its primary endpoint. In the mITT population, LS mean DA ratio was 0.83 (95% CI: 0.77, 0.88) for the Wave PRO device and 0.57 (95% CI: 0.52, 0.62) for the predicate ACS device (p<.0001). The Wave PRO device exceeded performance with the difference of 0.26 compared to the predicate device, far exceeding the non-inferiority margin of -0.15. The Wave PRO System was therefore determined to be non-inferior to the predicate ACS.
- Results, Safety:** There were no adverse events, serious or otherwise, that occurred during the WaveCRESST study.

- **Conclusions:** The WaveCRESST study met its primary endpoint and demonstrated that the Wave PRO System was non-inferior to the predicate device with respect to effectiveness. There were no adverse events. The Wave PRO System was therefore shown to be safe and effective in this study.

VIII. Special Controls

The Pression Wave PRO External Counter-Pulsation System meets the special controls specified in 21 CFR 870.5225, External counter-pulsating device.

IX. Conclusions and Benefit/Risk Assessment

Based on the nonclinical and clinical testing summarized in this 510(k), the Pression Wave PRO External Counter-Pulsation System is as safe, performs as well as, and is at least as effective as the predicate device. Data from the WaveCRESST clinical study indicates that the Wave PRO System is non-inferior to the predicate device with respect to effectiveness based on DA ratio. There were no adverse events in the clinical study, and nonclinical testing and risk management have determined that the risk of the Wave PRO System has been reduced as far as possible. The Wave PRO System is at least as safe as the predicate device.

The clinical benefits of ECP treatment in patients with chronic stable angina are well documented in the literature. Given that the Wave PRO System has been shown safe and effective in nonclinical and clinical testing, the expected benefits of the device outweigh any risks.

Pression concludes that the Pression Wave PRO External Counter-Pulsation System is substantially equivalent to the predicate device, K042413, and the reference devices, K190683, K022107 and K152115. The Pression Wave PRO External Counter-Pulsation System does not raise any new issues or concerns of safety or effectiveness and is at least as safe and effective as the predicate device.