March 9, 2023

ZOLL Circulation, Inc.
Elizabeth Haines
Senior Director, Regulatory Affairs
2000 Ringwood Avenue
San Jose, California 95131

Re: K221700
Trade/Device Name: AutoPulse NXT Resuscitation System
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class II
Product Code: DRM
Dated: February 6, 2023
Received: February 7, 2023

Dear Elizabeth Haines:

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,

Kathleen M. Grunder -S

Digitally signed by Kathleen M. Grunder -S
Date: 2023.03.09 16:47:19 -05'00'

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221700

Device Name
AutoPulse NXT Resuscitation System

Indications for Use *(Describe)*

The AutoPulse NXT Resuscitation System is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by a lack of spontaneous breathing and pulse. The AutoPulse NXT System must be used only in cases where chest compressions are likely to help the patient.

The AutoPulse NXT System is intended for use as an adjunct to manual CPR when effective manual CPR is not possible (e.g., during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR).

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.

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510(k) Summary

Sponsor Information:

ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131

Contact Person:

Brian Robey
Vice President, Advanced Development
& Design Quality Assurance
Phone: (978)-805-9015
E-mail: brobey@zoll.com

Date of Summary: March 9, 2023

Device Name and Classification:

Trade/Proprietary Name:	AutoPulse® NXT Resuscitation System
Common Name:	Automatic Mechanical Chest Compressor
Regulatory Class:	Class II
Classification Name:	External Cardiac Compressor (21 CFR 870.5200)
Product Code:	DRM

Predicate Device(s):

Trade/Proprietary Name:	AutoPulse® Resuscitation System Model 100
Common Name:	Automatic Mechanical Chest Compressor
Regulatory Class:	Class II
Classification Name:	External Cardiac Compressor (21 CFR 870.5200)
Product Code:	DRM
510(k) Number:	K112998 (Cleared: March 15, 2012)

Device Description

The AutoPulse® NXT Resuscitation System (also referred to as the AutoPulse® Model 200 or AP 200 System) is an automatic, portable, battery-powered chest compressor, which provides chest compressions as an adjunct to performing manual cardiopulmonary resuscitation (CPR). The system can adjust to different patient sizes and can operate in environments with limited space, such as moving vehicles.

The system may be a reasonable alternative to conventional CPR in specific settings where the delivery of high-quality manual compressions may be challenging or dangerous for the provider (e.g., during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR).

The AutoPulse® NXT Resuscitation System (hereinafter referred to as AutoPulse® NXT System) consists

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of four (4) primary components: a reusable platform (AutoPulse® NXT Platform), a single-use chest compression assembly (AutoPulse® NXT Band), a rechargeable battery (AutoPulse® NXT Battery), and a reusable battery charger (AutoPulse® NXT Battery Charger).

The AutoPulse® NXT Platform contains the mechanical drive mechanism, control system, software, and electronics necessary to generate and control the motion required to perform mechanical chest compressions. User controls and indicators are contained in two (2) identical User Control Panels provided for ease-of-use.

The AutoPulse® NXT Band is a chest compression assembly which consists of a cover plate and two bands integrated with a compression pad with a Velcro fastener. Attached to the AutoPulse® NXT Platform, the NXT Band is automatically adjusted to the patient and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest. The band is a single-use component that is attached to the AutoPulse® NXT Platform before each use.

The Lithium-ion (Li-ion) Battery is a removable component that supplies power for operation of the AutoPulse® NXT Platform. It also includes a printed circuit assembly to provide "smart battery" features including cell balancing, state of charge (SOC) reporting, a history archive, and safety circuits.

The AutoPulse® NXT Battery Charger is a reusable, stand-alone unit intended to charge and test-cycle AutoPulse® NXT Batteries. The battery charger has two (2) charging bays, each with its own indicators, and is used to charge and test-cycle up to two (2) AutoPulse® NXT batteries simultaneously. When in use, the battery charger continuously tests itself and any compatible batteries in its ways.

The AutoPulse® NXT System comprises the subject devices included in this 510(k).

Indications for Use

The AutoPulse® NXT System is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by a lack of spontaneous breathing and pulse. The system must be used only in cases where chest compressions are likely to help the patient.

The system is intended for use as an adjunct to manual CPR when effective manual CPR is not possible (such as during patient transport or extended CPR when fatigue may prohibit the delivery of effective or consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR).

Comparison of Technological Characteristics

The AutoPulse® NXT System is a battery-powered external chest compressor that utilizes a load- distributing compression band to circumferentially compress the entire thorax to provide blood flow during cardiac arrest. The principles of operation are substantially equivalent between the predicate AutoPulse® Resuscitation System Model 100 and subject device, AutoPulse® NXT System. A high-level comparison of technological characteristics is provided in **Table 5-1**.

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Table 5-1: Comparison of Technological Characteristics		
Features/Functionalities	**Predicate Device**	**Proposed Device**
	AutoPulse® Resuscitation System Model 100	**AutoPulse® NXT System**
510(k) Number	K112998	K221700
Device Class	II	Same
Classification Regulation	21 CFR 870.5200 – External Cardiac Compressor	Same
Product Code	DRM	Same
Indications for Use	The AutoPulse® Resuscitation System Model 100 is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by lack of spontaneous breathing and pulse.	The AutoPulse® NXT System is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by a lack of spontaneous breathing and pulse. The system must be used only in cases where chest compressions are likely to help the patient. The AutoPulse® NXT System is intended for use as an adjunct to manual CPR when effective manual CPR is not possible (e.g., during patient transport or extended CPR when fatigue may prohibit the delivery of effective or consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR).
Target Patient Population	Clinically dead adults as defined by a lack of spontaneous breathing and pulse.	Same
Min. Patient Chest Width	9.8"	Same
Patient Chest Circumference	Minimum: 30" Maximum: 51.2"	Minimum: Same Maximum: 56"
Maximum Patient Weight	300 lbs.	400 lbs.
Intended Environment	Point of Rescue, Ambulance, Hospital, Nursing home, Health Care Facility	Same
Operating Temperature	Temperature: 0 – 40° C Relative Humidity: 5 – 95% non-condensing relative humidity	Temperature: 0 – 45° C Relative Humidity: 15 – 95% non-condensing relative humidity
System Components	Platform, Band, Battery, Battery Charger	Same
Single-Use/Reusable	• Platform: Reusable • Band: Single-Use	Same

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Table 5-1: Comparison of Technological Characteristics		
Features/Functionalities	**Predicate Device**	**Proposed Device**
	AutoPulse® Resuscitation System Model 100	**AutoPulse® NXT System**
	• Battery: Reusable • Battery Charger: Reusable	
Sterility	Non-sterile	Same
Prescription Use Only	Yes	Same
Energy Source	• Platform: Battery-powered • Band: N/A – non-active • Battery: A/C Mains • Battery Charger: A/C Mains	Same
Patient Contact	• Platform: Direct (limited) • Band: Direct (limited) • Battery: None • Battery Charger: None	Same
Patient Contact Materials	• Platform: Thermoplastics • Band: Tyvek, thermoplastic	• Platform: Thermoplastics • Band: Tyvek, thermoplastic There are some differences in the type of thermoplastics utilized for the proposed device. The change in materials was sought to aide improvements in manufacturability for the proposed design. Materials used in the manufacture of both devices have been used in numerous medical applications and have well-established material safety profiles. In addition, 10993-1 testing confirms that the proposed device materials are biocompatible.
Fundamental Technological Characteristics	Compression Frequency: 80 ± 5 compressions per minute	Same
	Compression Depth: Chest displacement during chest compression equal to 20% reduction in anterior-posterior chest depth for each patient, +0.25/-0.5 inches.	Compression Depth: Chest displacement during chest compression equal to 20%, up to 2.1 +0.25/-0.5 inches reduction in anterior-posterior chest depth for each patient.
	Compression Modes: 30:2; 15:2; Continuous	Compression Modes: 30:2; Continuous
	Physiologic Duty Cycle: 50 ± 5%	Same
Platform	The platform contains the drive mechanism, electronics, sensors, and support means for the patient.	Same
	Compressions are provided by tightening and releasing the band across the patient's sternum	Same

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Table 5-1: Comparison of Technological Characteristics		
Features/Functionalities	**Predicate Device**	**Proposed Device**
	AutoPulse® Resuscitation System Model 100	**AutoPulse® NXT System**
	Patient baseline and compression depth is determined and controlled via load cell.	Patient baseline and compression depth is determined and controlled via motor current.
	User Control Panel: • Panel type: LCD screen with several buttons and prompts available to user to operate the system. • Quantity: One (1) control panel placed on the side of the device.	User Control Panel: • Panel type: Simple non-LCD user interface designed to be glanceable and intuitive, minimizing the physical, cognitive, and visual workload on users. • Quantity: Two (2) identical user control panels added to both sides of the platform to provide users access from either side of the patient.
Band	Single-use, non-sterile band that provides the mechanism of applying compressions to the chest and consists of a compression band and straps.	Same
	Patient position when changing band: Patient must be off the platform.	Patient position when changing band: Patient can be either on or off the platform.
Battery	Rechargeable Lithium-Ion battery	Same
Battery Charger	Capable of charging both the original cleared nickel metal hydride (NiMH) battery and the Li-Ion Battery.	Capable of charging only the proposed Li-Ion Battery.

Substantial Equivalence – Non-Clinical Evidence:

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

Software Verification and Validation

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submission for Software Contained Medical Devices*, published on May 11, 2005. The software for this device was considered as a "Major" level of concern, as a failure or latent flaw in the software could result in serious injury or death to the patient. Extensive performance testing in the form of the software verification and system level validation ensured that the AutoPulse® NXT System performs as well as the indicated predicate device and met all of its functional requirements and performance specifications.

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Software verification protocols were created to verify each requirement in the Software Requirements Specification (SRS) document. Protocols may use test, analysis, or inspection as acceptable methods of requirements verification.

Safety testing per the international recognized standards

The device was evaluated and found to be in compliance with the standards identified in **Table 5-2**.

Table 5-2: AutoPulse® NXT System Standards

Standard Designation	FDA Recognized Consensus Number
General Medical Device	
ISO 13485:2012 Edition	Not Recognized (N/R)
ANSI AAMI ISO 14971:2007/(R)2016	5-40
IEC 60812 Edition 2.0	N/R
EN 1789:2020	N/R
Transport, Environmental, and Storage	
IEC 60068-2-1 Edition 6.0	N/R
IEC 60068-2-2 Edition 5.0	N/R
IEC 60068-2-6 Edition 7.0	N/R
IEC 60068-2-13:1983	N/R
IEC 60068-2-27 Edition 4.0	N/R
IEC 60068-2-30 Edition 3.0	N/R
IEC 60068-2-31 Edition 2.0	N/R
IEC 60068-2-47 Edition 3.0	N/R
IEC 60068-2-78 Edition 2.0	N/R
IEC 60068-2-64 Edition 2.1	N/R
IEC 60529 Edition 2.2	N/R
UN3480:2014	N/R
Electrical and Battery	
EN 61959:2004	N/R
IEC 62133-2 Edition 2.0 (2012-12)	19-13
UN38.3 Edition 7.0	N/R
EN 55011 CISPR-11:2009	N/R
CISPR-14-1:2005	N/R
CISPR-16-1-1 Edition 5.0	N/R
CISPR-16-1-2 (2003+2004+2006 Edition 2.1)	N/R
IEC 60073 Edition 6.0	N/R
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/ (R)2012	19-4
IEC-60601-1-2:2014 Edition 4.0	19-8
EN 301 489-1 V2.2.3	N/R
EN 301 489-17 V3.2.4	N/R
AIM Standard 7351731 Rev. 2.00 (2017-02-23)	19-30
AAMI TIR69: 2017/(R2020)	19-22

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Table 5-2: AutoPulse® NXT System Standards	
Standard Designation	**FDA Recognized Consensus Number**
IEC 60601-1-6 Edition 3.1 (2013-10)	5-89
IEC 60601-1-9 Edition 1.1	N/R
IEC 60601-2-2 Edition 5.0	N/R
IEC 60601-2-4 Edition 3.1 (2018-02)	3-169
IEC 60601-2-27 Edition 3.0 (2011-03)	3-126
IEC 60601-2-47 Edition 2.0 (2012-02)	3-155
IEC 60601-2-49 Edition 2.0	N/R
IEC 61000-3-2 Edition 3.2	N/R
IEC 61000-4-11 Edition 2.0	N/R
IEC 61000-4-2 Edition 2.0	N/R
IEC 61000-4-3 Edition 3.2	N/R
IEC 61000-4-4 Edition 3.0	N/R
IEC 61000-4-5 Edition 3.0	N/R
IEC 61000-4-6 Edition 4.0	N/R
IEC 61000-4-8 Edition 2.0	N/R
IEC 61960:2011	N/R
IEC 62281 Edition 2.0	N/R
IEC 62353 Edition 2.0	N/R
Materials	
ANSI AAMI ISO-10993-1:2018	2-258
IEC 60085:2007	N/R
Human Factors/Usability	
ANSI AAMI IEC 62366:2015	5-114
ISO/TR 7250-1:2008	N/R
ISO/TR 7250-2:2010	N/R
Software	
ANSI AAMI IEC 62304:2006/A1:2016	13-79
Labeling	
ISO 20417 First edition (2021-04)	15-135
ANSI AAMI ISO 15223-1:2016	5-117
IEC/TR 60878 Ed. 3.0 b:2015	5-104

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Table 5-2: AutoPulse® NXT System Standards	
Standard Designation	**FDA Recognized Consensus Number**
IEC 60417:2002 DB	5-102

Safety testing ensures that the device complies with applicable sections of recognized industry and safety standards. Applicable testing was completed to provide objective evidence of compliance to the aforementioned standards.

Usability Testing

Formative and summative human factors analyses were conducted for the proposed AutoPulse® NXT System. The testing demonstrates the results of Human Factors Engineering (HFE) and Usability Engineering (UE). This report discusses key findings from preliminary analyses and formative evaluations and how they were incorporated into the design, as well the final outcome of Summative Usability Testing and analysis of any residual risk.

Based on the findings of the Summative Usability Test, the AutoPulse® NXT System (AP 200) was found to be safe and effective for the intended users, uses, and use environments with acceptable residual risk.

This determination is based on application of human factors and usability engineering processes throughout design and development of the system, including:

- Items addressed from preliminary analyses and formative evaluations.
- Results of ZOLL's use-related risk-based comparison of the predicate device user interface (AP 100) to the proposed device (AP 200).
- Results of HF validation testing of the AutoPulse® NXT System, which collected performance, subjects' interview, and critical knowledge task data under simulated use conditions.
- Results of ZOLL's cross-functional risk-based review of the use-related hazards of the AutoPulse® NXT System.

The residual risks will continue to be evaluated based on the available data generated both internally and externally through our established feedback systems. At this time, all identified risks have been reduced as far as possible (RAFAP), and the overall residual risk is acceptable.

Substantial Equivalence – Clinical Evidence

Clinical evidence was not necessary to show substantial equivalence.

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Conclusion

The information presented in this 510(k) demonstrates that the proposed AutoPulse® NXT System is substantially equivalent to its predicate AutoPulse® Resuscitation System Model 100. Objective evidence is provided to show the proposed device meets its design, performance, and safety specifications, such that it will consistently operate safely and effectively if used as intended in the patient care environment. Furthermore, performance data demonstrates that the features and functions of the proposed device are substantially equivalent, in safety and effectiveness, to those of the predicate device.