March 18, 2023

Archeon
% Catherine Gloster
President
Gloster Biomedical International LLC
577 North Hope Ave
Santa Barbara, California 93110

Re: K221841
Trade/Device Name: EOlife
Regulation Number: 21 CFR 868.5915
Regulation Name: Ventilator, Emergency, Manual (Resuscitator)
Regulatory Class: Class II
Product Code: BTM
Dated: February 10, 2023
Received: February 13, 2023

Dear Catherine Gloster:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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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)*
K221841

Device Name
EOlife

Indications for Use *(Describe)*
EOlife is intended for use with emergency manual resuscitation devices to measure ventilatory flows and display visual guide on the insufflated volume, tidal volume, and ventilation frequency to ensure adequate ventilation of adult cardiopulmonary arrest patient during cardiopulmonary resuscitation (CPR) performed by healthcare professionals.

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

I. SUBMITTER

Date prepared: March 18, 2023
Company name: Archeon Medical
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Contact person: Ms. Valentine Oqda, Quality and Regulatory Affairs Director
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II. DEVICE

Trade name: EOlife
Common name: EOlife
Classification name : Manual Emergency Ventilator (21 CFR 868.5915)
Device class: Class 2
Product code: BTM

III. PREDICATE DEVICE

This submission establishes the substantial equivalence of the EOlife device to the predicate device:

- L770-CPR Resuscitation Timer, K062080 (Allied Healthcare Products) (BTM, 21 CFR 868.5915)

The following two reference devices were also used to support the substantial equivalence:

- Real BVM Help, P160022/S013 (Zoll) (MKJ, 21 CFR 870.5310)
- Exhalometer, K051279 (Caldyne) (BZK, 21 CFR 868.1850)

IV. DEVICE DESCRIPTION

EOlife is a medical device dedicated to healthcare professionals to help them providing manual ventilation during cardiopulmonary resuscitation (CPR).

EOlife is intended to be connected to any standard manual resuscitator for adults including a bag and a mask or endotracheal tube (ET tube) and supraglottic airway (SGA) device and to be used during manual ventilation of an adult cardiopulmonary arrest patient.

EOlife is a portable device composed of an electronic control unit including an embedded software, a removable and rechargeable battery pack and of a single use flow sensor: FlowSense.
EOlife does not present direct contact with the patient. Only the ventilation air flow is in contact with the internal part of FlowSense (indirect contact with the patient).

During manual ventilation, EOlife measures the ventilation parameters (insufflated volumes, tidal volumes, ventilation frequencies,) and gives real-time feedback to the user about the quality of the ventilation provided to the patient compared to the 2020 AHA (American Heart Association) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Part 3: Adult Basic and Advanced Life Support. The aim is to help the user ventilate according to the recommended frequencies (10 cycles per minute) and volumes (6-8 ml/kg of ideal body weight).

V. INDICATIONS FOR USE

EOlife is intended for use with emergency manual resuscitation devices to measure ventilatory flows and display visual guide on the insufflated volume, tidal volume, and ventilation frequency to ensure adequate ventilation of adult cardiopulmonary arrest patient during cardiopulmonary resuscitation (CPR) performed by healthcare professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

EOlife is substantially equivalent to its predicate device. Some of the device characteristics are supported by the reference devices.

The Table 1 provides a comparison between EOlife and its predicate device.

Table 1: Substantial equivalence with predicate device

-	Subject device	Predicate device	Discussion
Manufacturer	ARCHEON	Allied Healthcare Products	/
Device Name	EOlife	L770-CPR Resuscitation Timer	/

-	Subject device	Predicate device	Discussion
510(K) Number	K221841	K062080	/
Regulation Number	21 CFR 868.5915	21 CFR 868.5915	/
Classification	Class II	Class II	/
Classification name	Manual Emergency Ventilator	Manual Emergency Ventilator	/
Indications for Use	EOlife is intended for use with emergency manual resuscitation devices to measure ventilatory flows and display visual guide on the insufflated volume, tidal volume, and ventilation frequency to ensure adequate ventilation of adult cardiopulmonary arrest patient during cardiopulmonary resuscitation (CPR) performed by healthcare professionals.	The L770-CPR Resuscitation Timer gives an audible and visual guide to the proper inspiratory time and (BPM) breaths per minute during emergency manual ventilation. Il displays the actual inspiratory time, (BPM) breaths per minute, and peak airway pressure.	**Same** The devices are all intended to be used as an adjunct tool to the manual resuscitator to measure the manual ventilation and provide real time feedback to the user.
Intended use/Claimed functionalities	Measurement, display and real time guidance of manual ventilation quality	Measurement, display and real time guidance of manual ventilation quality	**Same**
Situation of use	CPR	CPR	**Same**
Intended patient	Adult cardiopulmonary arrest patient	Adult and child cardiopulmonary arrest patient	**Partial** Subject device is not intended for child, however there is no impact on substantial equivalence or safety and performance of the device. The intended use patient to adult only is supported by the reference device Real BVM Help (P160022/S013) which is also only intended for adult cardiopulmonary arrest patients
Ventilation interface	Mask or endotracheal tube (ET) or supraglottic airways (SGA) device	Mask only	**Partial** The interface with ET tube or SGA device is supported by both reference devices (Real BVM Help P160022/S013 and Exhalometer K051279) which may be used with mask or ET tube or SGA device
Design	Portable electronic control unit including sensors, an embedded software that contains algorithms and a screen to display information to the user	Portable electronic control unit including sensors, an embedded software that contains algorithms and a screen to display information to the user	**Same**
Materials	Plastic material	Plastic material	**Same**

-	Subject device	Predicate device	Discussion
Measurement technology	Flowmeter	Manometer	**Different** Type of sensor and resulting measured ventilation parameters are different due to the evolution of AHA guidelines which recommend now to control the volume of air administered to the patient. There is no impact on substantial equivalence or safety and performance of the device. Using flowmeter technology for the sensor is supported by both reference devices (Real BVM Help P160022/S013 and Exhalometer K051279) which both use flowmeter sensors
Ventilation parameters display	Ventilation frequency (Freq in cycle/min) Insufflated volume (Vi in mL) Tidal volume (Vt in mL)	Ventilation frequency (Freq in breath/min) Airway pressure (pressure in cm H2O) Inspiratory time (Ti in s)	**Partial** Type of sensor and resulting measured ventilation parameters are different due to the evolution of AHA guidelines which recommend now to control the volume of air administered to the patient. There is no impact on substantial equivalence or safety and performance of the device The ventilation parameters displays are supported by the reference devices: Real BVM Help (P160022/S013) displays the insufflated volume (Vi) then converted into the tidal volume (Vt) and the Exhalometer (K051279) displays the exhaled volume (Ve) converted into the tidal volume (Vt)
Ventilation modes	- 30:2 - Continuous	- 30:2 - Continuous	**Same**
Real time emergency feedback	2020 AHA (American Heart Association) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Part 3: Adult Basic and Advanced Life Support	2005 AHA (American Heart Association) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Part 3: Adult Basic and Advanced Life Support	**Same** Both devices were based on the current relevant AHA guideline in force
Power supply	Battery	Battery	**Partial**

-	Subject device	Predicate device	Discussion
	(lithium)	(Alkaline)	Both devices (Real BVM Help P160022/S013 and Exhalometer K051279) are powered with a battery using different technologies. There is no impact on substantial equivalence or safety and performance of the device. The use of a lithium battery is supported by both reference devices which use a lithium battery
Intended user	Healthcare professionals	Emergency medical team	**Same** Emergency medical team are healthcare professionals
Environment of use	- Prehospital care - Emergency transport - Hospital environment	- Emergency transport - Hospital environment	**Partial** Predicate device is not intended for prehospital care (outdoor environment conditions), but subject device is certified for this type of environment. There is no impact on substantial equivalence or safety and performance of the device. Prehospital care environment is supported by the reference device Real BVM Help (P160022/S013) which may be used in the same environment.
Measuring range and accuracy of ventilation values	Vi: Operating range 50 to 2000 ml RMSE = 15.7 ml Vt: Operating range 0 to 2000 ml RMSE = 40 ml	Ti: ± 10% Air pressure: 60 cm H_2O maximum ± 5%	**Same** The order of magnitude of the measuring accuracy of the ventilation parameters is the same
Measuring range and accuracy of ventilation frequencies	1 to 60 bpm ± 1 bpm	Unknown measuring range ± 1 bpm	**Same tolerance**

VII. PERFORMANCE DATA

Data provided in this submission indicate that the basic functional characteristics of EOlife are substantially equivalent to those of the predicate device. Test data also demonstrated

that the device is safe and effective and works according to its indications for use as well as meeting the requirements of the device's design specifications.

Non-clinical testing:
Bench testing related to software, hardware, biocompatibility, and performance including applicable consensus standards were conducted on EOlife, demonstrating the design meeting the specifications and the substantial equivalence of EOlife with the predicate device. Table 2 provides a summary of the non-clinical testing performed with EOlife.

Table 2: Summary of Performance Testing

Performance Testing	Summary
Biocompatibility	ISO 18562-1, -2 and -3 testing met requirements for breathing gas pathways: indirect patient contact (contact with airflow), limited exposure (<2 hours) ISO 10993-1 testing: surface contact for limited duration (<24 hours)
Electrical safety	IEC 60601-1 testing met requirements of the standard
Electromagnetic compatibility	IEC 60601-1-2 testing met requirements of the standard
Lithium battery	Certified according to IEC 62133-2 and UN 383 and UL 1642
Power supply	Certified according to EN IEC 61204-3 and EN 62368-1
Mechanical testing	IEC 60601-1-12 testing met requirements of the standard ISO 5356-1 testing met requirements for conical connection of anesthetic and respiratory equipment
Software	IEC 62304 testing met requirement of the standard. Software testing included software design, development, verification, validation, and traceability. Verification and validation demonstrated that the software functions correctly as designed and operates the device according to the device design specifications and requirements.
Performance Testing – Bench	Bench testing was performed to evaluate the performance of EOlife and to demonstrate the design meets the specifications. Bench testing included: - Verification of the mechanical design and compatibility of the device with its environment and with the manual resuscitator, - Accuracy assessment of the values measured and displayed by EOlife - Comparison between features (mechanical design, assembly with patient interface and manual resuscitator, ventilation setting), measurement technologies and displayed values/visual interface and ventilation feedback/guidance of EOlife and predicate device to demonstrate the substantial equivalence.
Performance Testing – Usability/Human factors	Usability assessment was completed for EOlife including critical tasks identification through use-based risk analysis, rounds of formative and summative testing according to IEC 62366-1 and 'Applying Human Factors and Usability Engineering to Medical Devices' FDA guidance. The study demonstrated that users were able to successfully and safely use the device.

Clinical performance testing:
The subject EOlife did not require clinical studies to support substantial equivalence.

VIII. CONCLUSION

Based on the comparison of the indications for use of EOlife, the proposed device and the predicate, and on the results of nonclinical testing, ARCHEON considers EOlife to be substantially equivalent to the predicate device.