SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Automated External Defibrillator

Device Trade Name: Avive AED, Avive AED Pad Cartridge, Avive AED Training Cartridge, Avive USB Charging Cable, Avive USB Power Adaptor

Device Procode: MKJ

Applicant's Name and Address: Avive Solutions, Inc.
223 Mississippi Street, Unit 2
San Francisco, CA 94107

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P210015

Date of FDA Notice of Approval: October 31, 2022

II. INDICATIONS FOR USE

The Avive Automated External Defibrillator (AED) is intended for emergency treatment of individuals who are exhibiting symptoms of cardiac arrest. A person in cardiac arrest:

- Is unresponsive; and
- Is not breathing normally.

The Avive AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock to treat ventricular fibrillation or pulseless ventricular tachycardia.

The Avive AED is indicated for adult and pediatric patients over 1 years of age. When a patient is less than 8 years old, or weighs less than 55 lbs., the Avive AED should be used in Child Mode. Otherwise, the Avive AED should be used in Adult Mode. Therapy should not be delayed in order to determine exact age and/or weight.

III. CONTRAINDICATIONS

Avive defibrillators should not be used if the patient is responsive or conscious.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Avive AED Owner's Manual.

V. DEVICE DESCRIPTION

Device Overview

The **Avive Automated External Defibrillator (AED)** is a fully automatic, portable, battery operated AED containing the components and functionality required to treat victims of sudden cardiac arrest. The device is used with the disposable and user-replaceable Avive Pad Cartridge that securely attaches to the Avive AED and houses two self-adhesive, single use, non-sterile electrode pads used for treatment.

The unit provides voice prompts and visual indicators suitable to guide trained and untrained users through a resuscitation sequence, which may include delivery of a defibrillation treatment and/or cardiopulmonary resuscitation (CPR). Upon activation, a user is instructed to apply the two electrode pads onto the bare skin of a patient who may be in cardiac arrest. Following placement of the electrode pads on a patient, the device records the patient's electrocardiogram (ECG), analyzes the cardiac rhythm, and distinguishes between shockable and non-shockable cardiac rhythms. The Avive AED delivers an impedance-compensating, biphasic, truncated exponential (BTE) waveform configurable for both adult and pediatric (under 55lbs or between the ages of 1 – 8 years old) therapy, providing effective treatment of Ventricular Fibrillation (VF) or pulseless Ventricular Tachycardia (VT). Following shock delivery (if appropriate), the device prompts the user to perform CPR.

The Avive AED is battery-powered via a rechargeable internal battery, and performs daily, weekly, and monthly self-tests to help ensure readiness for use. A status light on the unit provides a visual indication of whether the device is functional or not fully functional. A training mode is supported via insertion of the Avive Training Cartridge, whereby a user can interact with the AED through training scenarios. The Avive AED software is designed with cybersecurity in mind by implementing a secure software update process, communication authentication, and integrity checks for reliable data transfer and safe communication.

Figure A provides an image of the Avive AED assembled with an Avive Pad Cartridge.

Figure A. Avive AED

Device Features

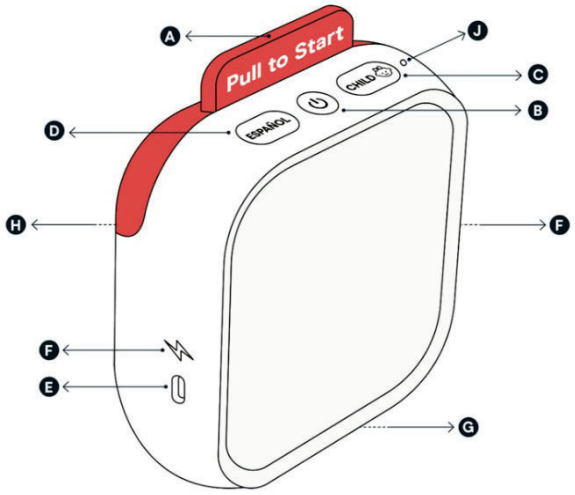

Figure B. Avive AED User Interface

Table A provides a detailed description of the user interface features of the Avive AED, referencing the labels in Figure B.

Table A. Avive AED User Interface

Label	User Interface	Description
A	Pull Tab	When pulled, the red tab reveals the packaged electrode pads, and automatically powers on the Avive AED. The electrodes can be used for both adult and pediatric patients.
B	Power Button	Pressing the power button powers the AED on or off. When the AED is on, this button is backlit, and when the AED is off this button is not backlit.
C	Child Button	Upon power on, the AED defaults to an adult energy level. Pressing the Child Button toggles the AED to a pediatric energy level. When set to the pediatric level, this button is backlit, and when set to the adult level, this button is not backlit. If the Child Button is pressed accidentally, the button can be pressed again to revert to an adult energy level. The pediatric energy level is intended for patients less than 8 years old, or weighing less than 55 lbs.
D	Español Button	Upon power on, the AED defaults to providing instruction in the English language. Pressing the Español Button toggles the AED to providing instruction in the Spanish language. When providing instruction in Spanish, this button is backlit, and when providing instruction in English, this button is not backlit. If the Español Button is pressed accidentally, the button can be pressed again to revert to the English language.
E	USB Charging Port	Used to recharge the AED's internal battery.
F	Stand Back Lights	Located on either side of the AED, these lights flash red when the device is analyzing the patient's heart rhythm or delivering therapy, indicating not to touch the patient.

Label	User Interface	Description
G	Speaker	Provides audio voice prompts to guide users through a resuscitation sequence.
H	Pad Cartridge	Contains two single use electrode pads used for treatment. The Pad Cartridge is user replaceable, and pulling the red tab reveals the sealed electrode pads.
J	Status Light	The Avive AED provides a Status Light that indicates whether the device is functional or not fully functional.

In addition to the user interface features described in Table A, the AED contains core features and characteristics as described in Table B.

Table B. List of Avive AED Features

Avive AED Features	Description
Defibrillation Waveform	The Avive AED delivers an impedance compensating, biphasic truncated exponential (BTE) waveform. The device has a non-escalating shock protocol that delivers a selected 150 J for adult patients and selected 50 J for pediatric patients.
Electrode Pads	The device is compatible with self-adhesive electrode pads housed within the Avive Pad Cartridge that are suitable for both adult & pediatric use. The pads are single-use, non-sterile, and user-replaceable.
Rhythm Recognition Detector	The device has a proprietary algorithm for detecting whether a patient has a shockable or non-shockable heart rhythm.
Adult / Pediatric Mode	The device allows the user to select whether the patient is an Adult or Pediatric patient via a button on the AED, which adjusts the defibrillation waveform accordingly.
Fully Automatic Defibrillator	The device is a fully automatic AED, and provides audible warning prior to The delivery of a defibrillation shock. Certain safety criteria must be satisfied before delivery of a shock.
Device Activation	The device is activated via a power button or by pulling the red tab of the Avive AED Pad Cartridge to reveal the packaged electrode pads.
Audible User Instruction	The device provides voice prompts and visual indicators suitable to guide trained, minimally trained, and untrained users through a resuscitation sequence. The device by default provides instruction in the English language and can be configured to provide instruction in the Spanish language via the Español Button on the AED.
Internal Self-Tests	The device performs daily, weekly, and monthly self-tests to help ensure readiness for use.
Visible Status Indicator	The device provides a Status Light that indicates whether the device is functional or not fully functional.
Training Mode	The device provides a Training Mode whereby a user can interact with the AED through training scenarios via installation of the Avive AED Training Cartridge.

Avive AED Features	Description
Software Updates	The device software can be updated, with security features built-in to prevent file corruption and risk due to cybersecurity.
Internal Rechargeable Battery	The device has a dedicated internal rechargeable battery that provides the power necessary for AED operation.
Backup Power Charging	If the device is needed for emergency use and has a discharged internal battery, the unit is operable with reduced performance when connected to an appropriate USB power source. This allows for audio instruction, ECG analysis, patient defibrillation, and overall operation of the device when treatment would otherwise not be available.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Defibrillation is the only currently available treatment for termination of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). Public access defibrillation is designed to provide potentially lifesaving treatment prior to the arrival of emergency personnel.

VII. MARKETING HISTORY

The Avive Automated External Defibrillator (AED) has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device and AEDs in general.

- Failure to identify shockable arrythmia;
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury;
- Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction;
- Myocardial damage;
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents;
- Incorrectly shocking a pulse sustaining rhythm and inducing cardiac arrest;
- Bystander shock from patient contact during defibrillation shock;
- Interaction with pacemakers;
- Skin burns around the electrode pad placement area;
- Skin reaction due to sensitivity to materials used in electrode pad construction; and
- Minor skin rash.

For the specific adverse events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

The Avive AED and accessories underwent bench evaluation, animal testing, biocompatibility evaluation, human factors and usability testing, as well as software verification and validation appropriate for devices having a major level of concern. Testing was conducted on key device subassemblies and the complete system.

The Avive AED conforms to various international standards, including:

- 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 – electromagnetic compatibility
- IEC 60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – usability
- IEC 60601-2-4, Medical Electrical Equipment – Part 2-4: General requirements for basic safety and essential performance of cardiac defibrillators
- IEC 62366, Application of Usability Engineering to Medical Devices
- IEC 62304, Medical device software – Software life cycle processes
- IEC 60601-1-11, Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

A. Laboratory Studies

Table C summarizes the major bench testing conducted to demonstrate safe and effective performance of the Avive AED System, including conformance to applicable international and consensus standards.

Table C. Bench Testing

Test	Purpose	Acceptance Criteria	Result
Basic Safety and Essential Performance (IEC 60601-1, IEC 60601-2-4)	Verify general requirements for the basic safety and essential performance of the device.	Compliance to the listed international standards.	Pass

Electromagnetic Compatibility (EMC) (IEC 60601-1-2)	Verify general requirements for the basic safety and essential performance of the device when subjected to electromagnetic disturbances.	Compliance to the listed international standards.	Pass
Medical Electrical Systems used in the Home Healthcare Environment (IEC 60601-1-11)	Verify general requirements for the basic safety and essential performance of the device when subjected to conditions of the home healthcare environment.	Compliance to the listed international standards.	Pass
Electrode Pad Biocompatibility (ISO 10993-1)	Verify cytotoxic, sensitization, and irritation requirements for the device.	Compliance to the listed international standards.	Pass
Shelf Life, Service Life and Reliability	Verify that the device meets product specifications throughout its labelled shelf / service life.	Product specifications are met following the conditioning and testing.	Pass
Packaging and Transportation	Verify packaging configurations provide adequate product protection.	Functional tests and visual inspections function as intended following testing of packaging configurations.	Pass
Software Verification & Validation	Verify software requirements and software functionality.	Software requirements and software functionality requirements are met.	Pass
AED System Functional and Performance tests	Verify that the device meets product specifications across a range of functional and performance requirements.	Product specifications for all functional and performance requirements are met.	Pass

i. Biocompatibility Testing

The only patient contacting portions of the Avive AED are the electrode pads contained in the Avive AED Pad Cartridge. The patient contacting materials of the electrode pads were tested in accordance with ISO 10993-5:2009 for cytotoxicity, and ISO 10993-10:2010 for irritation and sensitization. All tests passed for biocompatibility.

ii. Shelf-Life, Service Life and Reliability

The Avive AED System (AED, Pad Cartridge, and accessories) is provided non-sterile.

Service life and reliability testing were conducted to demonstrate the labeled service life for the AED.

Accelerated shelf life testing was conducted to demonstrate the labeled shelf life for the Pad Cartridge.

iii. Packaging and Transportation

Packaging configurations for the Avive AED, Avive AED Pad Cartridge, and accessories were functionally tested after environmental conditioning, storage and shipping simulations. All tests passed for transportation, distribution, and packaging tests.

iv. Software Verification and Validation

The Avive AED software is defined as a Major level of concern according to the FDA guidance document entitled, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*," issued May 11, 2005. Software was developed and validated according to IEC 62304:2015. Documentation includes software level of concern, software description, hazard analysis, software FMEA, software requirements specification, software architecture diagrams, software design specifications, requirements traceability matrix, software development environment description, verification and validation documentation, revision level history, unresolved anomaly report, discussion of tools to detect run-time errors, and cybersecurity documentation.

Software verification and validation testing conducted on the Avive AED included unit, integration, and system-level protocols and test reports with pre-defined pass/fail criteria. This testing demonstrated that the software in the Avive AED performed as intended.

B. Animal Studies

A GLP animal study is provided to support the reasonable assurance of safety and effectiveness of the Avive pediatric defibrillation waveform in the pediatric sub-population of children 1 to 8 years old. The study demonstrated that the Avive pediatric defibrillation waveform successfully defibrillated all animals in the pediatric animal model, without any safety related observations or concerns.

i. Pediatric Defibrillation Waveform – Non-Clinical Animal Study

The Avive pediatric waveform is an impedance-compensating, biphasic truncated exponential waveform with a selected energy of 50 J (non-escalating). A GLP animal study was conducted in two phases to validate the safety and effectiveness of the Avive pediatric waveform using a porcine model for pediatric patients between 1 and 8 years of age.

ii. Safety phase

Animal testing was performed on a total of 8 piglets weighing 10 – 24 kg. Four animals were assigned to the test (Avive) group, and four animals were assigned to the control (Philips) group. Following ~30 seconds of untreated ventricular fibrillation, all 8 animals were successfully resuscitated on the first defibrillation shock with a 50 J shock. Animals were survived for 24 hours, with blood panels taken periodically. Comparison of blood panels between the test and control devices found no significant differences in elevation of cardiac enzymes, or parameters indicative of cardiac tissue damage. There was no clinically significant abnormal clinical pathology, daily observations, macroscopic, or microscopic findings attributed to the use of the device in a 24-hour porcine model.

iii. Effectiveness Phase

The objective of this phase was to establish whether the Avive pediatric waveform was comparable to known performance criteria expected of pediatric defibrillation waveforms. Animal testing was performed on a total of 6 piglets weighing 10 – 24 kg. Ventricular fibrillation was induced, and defibrillation was attempted following ~30 seconds of untreated ventricular fibrillation. A total of 8 inductions were conducted on each animal. There were 48 first shocks delivered, of which 45 or 94% achieved Return of Spontaneous Circulation (ROSC) within the first defibrillation shock. A total of 47/48 achieved ROSC within 2 defibrillation shocks, and 48/48 achieved ROSC within 3 defibrillation shocks. Neither CPR nor emergency medication were administered to any animals during the procedures. The study results rejected the null hypothesis that the Avive pediatric waveform was inferior to known performance criteria expected of pediatric waveforms and resulted in a 95% Confidence Interval of 92.6% – 100% with a non-inferiority p-value of 0.0004.

C. Additional Studies

i. Rhythm Recognition Detector

The rhythm recognition detector is a neural network algorithm used to assess whether a patient has a shockable or non-shockable heart rhythm. The algorithm was developed using non-overlapping training, validation, and test datasets comprised of ECG rhythms from a variety of data sources that make up Avive's internal ECG database of over 23,000 recordings. Demographic information for patient records in the ECG database is limited given the use case of a defibrillator, however, all datasets have a nearly equal number of male to female patient records, a representative range of patient age, and are collected from representative use scenarios to what the Avive AED is expected to encounter in field use. Final performance testing, reported in Table D, is evaluated using Avive's internal ECG Test Dataset comprised of rhythms collected from defibrillators using representative multifunction electrodes. The final performance testing utilizes only one record per person. The Avive AED meets the requirements of IEC 60601-2-4 and the performance goals established by the guidance from the American Heart Association (AHA) for arrythmia analysis algorithms.[1]

[1] Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety A Statement for Health Professionals From the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation. 1997;95(6):1677-1682.

Table D. Rhythm Recognition Performance Results

Rhythm	Test Sample Size	Performance Goal	Observed Performance	90% One-Sided Lower Confidence Limit
Shockable				
Coarse V-Fib	274	>90% sensitivity	98.9% sensitivity	97.9%
Rapid V-Tach	101	>75% sensitivity	99.0% sensitivity	97.4%
Non-Shockable				
NSR	137	>99% specificity	100% specificity	100%
AF, SB, SVT, Blockage, Idioventricular, PVC's	288	>95% specificity	99.3% specificity	98.5%
Asystole	105	>95% specificity	100% specificity	100%
Intermediate				
Fine VF	80	Report Only	92.5% Shock	-
Other VT	66	Report Only	86.4% Shock	-

ii. Adult Defibrillation Waveform

The Avive adult waveform is an impedance-compensating, biphasic truncated exponential waveform with a selected energy of 150 J (non-escalating). A comparison demonstrating the similarity of the Avive adult waveform to the Philips adult waveform was completed, supporting the use of published clinical data in support of the Avive adult defibrillation waveform.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

A. Study Design

The final order entitled, "Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems," published by Food and Drug Administration on January 29, 2015 and republished on February 3, 2015, states that clinical study information can be leveraged for AEDs from both published studies and clinical data previously submitted to FDA under the 510(k) process. A comparison demonstrating the similarity of the Avive adult waveform to the Philips adult waveform was performed. Both devices deliver an impedance-compensating, biphasic truncated exponential waveform with a selected energy of 150 J. The comparison provides a side-by-side comparison of the waveforms delivered into simulated patient loads of 25 Ω – 200 Ω in 25 Ω increments, including:

- Side-by-side oscilloscope capture of the voltage waveform;
- Side-by-side oscilloscope capture of the current waveform;
- Detailed parameters of both the Avive and Philips waveforms, including:
  - Delivered energy of the waveform;
  - Peak current of the first and second phase of the waveform;
  - Peak voltage of the first and second phase of the waveform;
  - Phase duration of the first and second phase of the waveform; and
  - Tilt percentage of the first and second phase of the waveform.

The Philips adult wave form safety and effectiveness was supported through published clinical data for defibrillation, including studies by Schneider et al., Poole et al., and White

et al and therefore, can be used to support the safety and effecteiveness of the Avive adult defibrillation waveform.

The comparison demonstrates that the waveforms are almost identical. Consequently, the clinical data used in support of the adult defibrillation waveform was leveraged from published clinical data.[2,3,4]

B. Safety and Effectiveness Results

i. Safety Results

The analysis of safety was based on the comparison to the Philips adult defibrillation waveform as discussed above X(A).

ii. Effectiveness Results

The analysis of effectiveness of the Philips biphasic adult waveform was based on the published clinical data for defibrillation, including studies by Schneider et al., Poole et al., and White et al.

1. Scneider et al. (2000)[2]

A prospective, multicenter, out-of-hospital clinical trial was conducted to support adult defibrillation by comparing AEDs that delivered 150 J biphasic shocks with AEDs that delivered high-energy 200 - 360 J monophasic shocks. The Schneider et al. study delivered a sequence of up to three defibrillation shocks for the biphasic devices (150 J – 150 J – 150 J). Monophasic units delivered 200 J – 200 J – 360 J shocks. Termination of VF for 5 seconds was the definition for defibrillation. Of 338 patients with an out-of-hospital cardiac arrest, 150 had a ardiac etiology, presented with VF, and were shocked with one of the AEDs. The results are summarized in Table E below.

Table E. Biphasic vs. Monophasic waveform, Schneider, et al.

	Biphasic Patients Number (%)	Monophasic Patients Number (%)	P Value
Defibrillation Efficacy			
1 shock	52/54 (96%)	36/61 (59%)	<0.0001
≤ 2 shocks	52/54 (96%)	39/61 (64%)	<0.0001
≤ 3 shocks	53/54 (98%)	42/61 (69%)	<0.0001
Patients defibrillated	54/54 (100%)	49/58 (84%)	0.003
ROSC	41/54 (76%)	33/61 (54%)	0.01
Survival to Hospital Admission	33/54 (61%)	31/61 (51%)	0.27
Survival to Hospital Discharge	15/54 (28%)	19/61 (31%)	0.69

[2] Schneider T, et al. Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared with 200-J to 360-J Monophasic shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims. Circulation. 2000;102:1780-1787. doi: 10.1161/01.CIR.102.15.1780.

[3] Poole J, et al. Low-Energy Impedance-Compensating Biphasic Waveforms Terminate Ventricular Fibrillation at High Rates in Victims of Out-of-Hospital Cardiac Arrest. Journal of Cardiovascular Electrophysiology. 1997;8:1373-1385.

[4] White R, et al. Transthoracic impedance does not affect defibrillation, resuscitation or survival in patients with out-of-hospital cardiac arrest treated with a non-escalating biphasic waveform defibrillator. Resuscitation. 2005;64(1):63–69. doi:10.1016/j.resuscitation.2004.06.02.

In the Schneider study, more adult patients were defibrillated with the biphasic waveform than a monophasic waveform (100% vs. 84%). A greater percentage of patients achieved return of spontaneous circulation (ROSC) after biphasic shock (76% vs. 54%). There was no statistical difference between the two waveforms for rates of survival to hospital admission and discharge.

2. Poole et al. (1997)[3]
   The performance of the 150 J impedance-compensating biphasic waveform was observed in the out-of-hospital setting on 100 consecutive victims of sudden cardiac arrest across 12 EMS systems. Data was obtained from the AED PC card reporting system. Continuous defibrillation was defined as conversion to an organized rhythm for 5 seconds or to asystole. Endpoints included: defibrillation efficacy of ventricular fibrillation (VF), restoration of an organized rhythm at the time of patient transfer to an advanced life support (ALS) team or to the emergency department (ED), and time from AED power-on to first defibrillation.

   A total of 202 VF episodes were handled in the 44 patients presenting with VF. A single 150 J biphasic shock defibrillated the initial VF episode in 39 of 44 (89%) patients. 95% terminated VF after two shocks, and 99% terminated with 3 shocks or fewer. At patient transfer to ALS or ED care, an organized rhythm was present in 34 of 44 (77%) of patients presenting with VF. Asystole was present in 7 (16%) and VF in 3 (7%). The average number of shocks delivered per initial VF episode was 1.2 ± 0.5. A very wide range of patient resistances (36 Ω to 171 Ω) was exhibited, confirming that automated impedance compensation maintains high efficacy without the need to either step-up energy levels or use high-energy shocks.

   The low-energy impedance-compensating biphasic waveform terminates long-duration VF at high rates in out-of-hospital cardiac arrest. Use of this waveform allows AED device characteristics consistent with widespread AED deployment and early defibrillation.

3. White et al. (2004)[4]
   Cardiac arrest data from two EMS systems were analyzed retrospectively, totaling 102 out-of-hospital-cardiac-arrest patients. All witnessed arrests from patients who presented with a shockable rhythm and were treated initially by BLS personnel were included. Both EMS systems employed fixed low-energy biphasic AEDs (Forerunner, Philips Medical Systems). For each defibrillation and resuscitation outcome variable, differences in mean transthoracic impedance for successful versus unsuccessful outcomes were tested, and the effect of a call-to-shock time on overall outcome was also examined.

Initial shocks defibrillated 90% of patients. Cumulative success with two shocks was 98% and with three shocks was 99%. Patient impedance ranged from 27 Ω to 152 Ω. First-shock success, cumulative success through two shocks, and cumulative success through the first-shock series were unrelated to transthoracic impedance, as were BLS ROSC, pre-hospital ROSC, hospital admission, and discharge. Consistent with previous findings, call-to-shock time was highly predictive of survival.

High impedance patients were defibrillated by the biphasic waveform used in this study at high rates with a fixed energy of 150 J and without energy escalation. Rapid defibrillation rather than differences in patient impedance accounts for resuscitation success.

iii. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

iv. Human Factors

Usability evaluation was performed throughout the development process. A summative usability study was conducted to support the conclusion that the user interface for the Avive AED System and associated labeling is safe and effective when used by trained and untrained lay users.

The study included trained Life Support Professionals (n=34) and untrained Lay Users (n=36). All participants were asked to use the Avive AED to resuscitate a simulated patient during a simulated emergency-use scenario. Participants in each group were split evenly between a simulated adult patient and simulated pediatric patient. After simulated emergency use, participants were asked to perform several tasks related to maintenance of the Avive AED and comprehension of the instructions for use.

The study results demonstrated that the Avive AED and associated labeling are safe and effective, from a usability standpoint, for the intended users, its intended use, and use environments.

C. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR Part 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. Avive presented three clinical studies to support safety and effectiveness, none of which were sponsored by Avive. None of the clinical investigators or study authors were full-time or part-time employees of

Avive, and none had disclosable financial interests/arrangement with Avive, as defined in 21 CFR Part 54.1(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Cardiovascular Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The effectiveness analysis is based on bench testing of the rhythm recognition detector, the comparison of the Avive adult defibrillation waveform, and animal testing of the Avive pediatric defibrillation waveform. The bench testing demonstrates that the rhythm recognition detector exceeds both the AHA recommendations and the IEC 60601-2-4 standard for the basic safety and essential performance of cardiac defibrillators, for sensitivity and specificity for detecting shockable and non-shockable arrythmias.

The similarity between the Avive adult defibrillation waveform and the waveform used in the Schneider et al., Poole et al., and White et al. studies supports the use of that publicly available data to support the clinical safety and effectiveness of the Avive adult waveform. Schneider et al. shows that more adult patients were defibrillated with the biphasic waveform than a monophasic waveform, and a higher percentage of patients achieved ROSC after biphasic shocks. Poole et al. shows that the low-energy impedance-compensating biphasic waveform terminates long-duration VF at high rates in out-of-hospital cardiac arrest. White et al. shows that high impedance patients were defibrillated by the biphasic waveform used in this study at high rates with a fixed energy of 150 J and without energy escalation.

Pediatric defibrillation is supported by Avive animal testing, which demonstrates high first shock success using an impedance-compensating, fixed energy 50 J biphasic truncated exponential waveform.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in clinical studies conducted to support PMA approval as described above. The risks of the device are mitigated based on non-clinical testing and data collected from the published literature. The results from the non-clinical testing performed on the Avive AED demonstrated appropriate electrical and mechanical safety, electromagnetic compatibility, biocompatibility, reliability, shelf life, ability to withstand distribution, software performance, and overall system performance. Animal testing of the Avive

pediatric defibrillation waveform demonstrated the safety of the 50 J waveform, which did not find any clinically significant abnormal clinical pathology, blood panels, macroscopic, or microscopic findings. Published clinical studies in support of the adult defibrillation waveform, along with summative human factors testing, further demonstrates the safety of the device.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in clinical studies conducted to support PMA approval as described above. AEDs are life-saving devices used in emergency situations. The benefit of early defibrillation is the survival of patients in sudden cardiac arrest. For every minute that passes between collapse of a patient in sudden cardiac arrest and defibrillation, survival rates decrease 7 – 10%.[5] AEDs have been extensively shown to have a high benefit for patients.

The magnitude of this benefit is either life or death. The published literature has no ability to predict which patients will experience a benefit or determine probability of benefit because of the differing pathophysiology of underlying cardiac arrest. The subpopulations have a high degree of heterogeneity of etiologies of cardiac arrest; therefore, variation in public health benefit cannot be determined. Likewise, the duration of effect is dependent on the underlying etiology and though valuable to the patient, is highly dependent on subsequent treatment of the underlying disease. Duration of effect is not related to the device.

The probable risks of the device are also based on data collected in a clinical studies conducted to support PMA approval as described above. Patients put a high value on this treatment because it has the potential to save their lives. Patients are therefore willing to accept the risks of this treatment to achieve the benefit. If the treatment provides timely successful defibrillation, the patient will survive a life-threatening cardiac arrest situation and will be able to seek further treatment.

This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that for sudden cardiac arrest victims the probable benefits outweigh the probable risks.

D. Overall Conclusion

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

XIII. CDRH DECISION

[5] American Heart Association. Rural and Community Access to Emergency Devices. AHA/HPFS/3/2013.

CDRH issued an approval order on October 31, 2022. The final clinical conditions of approval cited in the approval order are described below.

1. The number of devices returned to the applicant for cause from domestic sources, with a breakdown into:
    a. Those returned for normal end-of-life; and
    b. Those returned with any alleged failures or malfunctions, including a summary of root causes and the frequency of occurrence for each identified root cause.

2. A summary of information available to you related to individual domestic uses of your device that may include, but is not limited to:
    a. Defibrillation success and the number of shocks required for success; and
    b. Identification of any error codes or malfunctions during use and their related MDR number.

3. A listing of any safety alerts, technical service bulletins, user communications, or recalls for devices under this PMA.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XV. REFERENCES

A. Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety A Statement for Health Professionals From the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation. 1997;95(6):1677-1682.
B. Schneider T, et al. Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared with 200-J to 360-J Monophasic shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims. Circulation. 2000;102:1780-1787. doi: 10.1161/01.CIR.102.15.1780.
C. Poole J, et al. Low-Energy Impedance-Compensating Biphasic Waveforms Terminate Ventricular Fibrillation at High Rates in Victims of Out-of-Hospital Cardiac Arrest. Journal of Cardiovascular Electrophysiology. 1997;8:1373-1385.
D. White R, et al. Transthoracic impedance does not affect defibrillation, resuscitation or survival in patients with out-of-hospital cardiac arrest treated with a non-escalating

biphasic waveform defibrillator. Resuscitation. 2005;64(1):63–69. doi:10.1016/j.resuscitation.2004.06.02.
E. American Heart Association. Rural and Community Access to Emergency Devices. AHA/HPFS/3/2013.