



October 31, 2022

Avive Solutions, Inc.  
% Darlene Crockett-Billig  
Regulatory Consultant, Co-Founder and President  
Experien Group, LLC  
224 Airport Parkway, Suite 250  
San Jose, California 95110

Re: P210015

Trade/Device Name: Avive Automated External Defibrillator (AED) System

Product Code: MKJ

Filed: April 6, 2021

Dear Darlene Crockett-Billig:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Avive Automated External Defibrillator (AED) System. 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 55lbs., 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.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has

determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

The expected shelf-life of the Avive AED has been established and approved at 7 years. Expiration dating of the Avive AED Pad Cartridge has been established and approved at 2.31 years when stored at nominal temperatures or a minimum of 1 year when stored at 35°C.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed to provide the following non-clinical information as part of the annual report, which may be followed by a PMA supplement where applicable.

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.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. The Avive AED post approval study is intended to confirm the safety and effectiveness of the Avive AED in the post-market setting. This is a prospective observational study comparing the Avive AED Rhythm Recognition Detector performance to objective performance criterion. The minimum sample size is collection of 200 cases with Coarse VF, in order to provide enough post-market data to satisfy the

minimum recommended sample size for Coarse VF in the Kerber et al. American Heart Association Guidance on Automatic External Defibrillation. It is estimated that 1,000 – 2,000 total patients will be required to achieve the minimum sample size for this PAS. No additional patient follow-up is required. The primary study endpoint for this PAS is a >90% sensitivity on Coarse VF rhythms for the Avive AED, with a 90% One-sided Lower Confidence Limit that is >87%. In addition to the ECG analysis performance, the PAS will also report the usability performance of the Avive AED represented by the time elapsed from AED activation to pads placed and if shockable, time to first shock delivered. Lastly, the PAS will also report the defibrillation shock performance of the Avive AED, including the number of shocks required for success. This was reviewed under the protocol provided via email on October 27, 2022. Avive proposes to provide FDA with a PAS Report every six (6) months for the first two (2) years and annually thereafter, beginning from the date of the approval letter for PMA P210015. In addition, an initial data submission will be provided following 25 uses of the device.

From the time of study protocol approval, you must meet the following timelines for the Avive AED post approval study.

- Submission of Final study report: 3 months from study completion (i.e. last subject, last follow-up date)

In addition, you must submit separate periodic reports on the progress of Avive AED post approval study as follows:

- PAS Progress Reports every six (6) months for the first two (2) years, and annually thereafter.
- An initial data submission following 25 uses of the device
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports (i.e., every 3 months), in addition to your periodic (6-months) PAS Progress Reports, until FDA notifies you otherwise.

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including the initiation, enrollment, and completion requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma\\_pas.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm).

In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (<https://www.fda.gov/media/71327/download>).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system>.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" <https://www.fda.gov/media/81431/download>.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> and on combination product post-marketing safety reporting is available at (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to

health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at

<https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Shruti Mistry at 301-796-6605 or [Shruti.Mistry@fda.hhs.gov](mailto:Shruti.Mistry@fda.hhs.gov).

Sincerely,

Jessica E. Paulsen -S

Jessica Paulsen

Director

Division of Cardiac Electrophysiology,

Diagnostics and Monitoring Devices

Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health