

# **SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)**

## **I. GENERAL INFORMATION**

Device Generic Name: Automated External Defibrillator

Device Trade Name: HeartStart OnSite Defibrillator (Model M5066A), HeartStart Home Defibrillator (Model M5068A), Primary Battery (Model M5070A), SMART Pads Cartridges (Adult Model M5071A) and Infant/Child (Model M5072A)

Device Procode: NSA, MKJ (pediatric pads)

Applicant's Name and Address: Philips Medical Systems  
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Bothell, WA 98021

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P160029

Date of FDA Notice of Approval: June 6, 2019

The HeartStart Home is an over-the-counter (OTC) home-use defibrillator and has been commercially available since 2004, when it was first cleared by FDA under K040904. The HeartStart OnSite is an OTC public access defibrillator and has been commercially available since 2002, when it was first cleared by FDA under K020715. P160029 has been submitted in response to the Final Order issued January 29, 2015, in the Federal Register Volume 80 Number 19, Docket No. FDA-2013-N-0234 and republished February 3, 2015, in the Federal Register Volume 80 Number 22, Docket No. FDA-2013-N-0234. The Final Order required premarket approval of marketed pre-amendment Class III Automated External Defibrillators (AED), product codes NSA and MKJ (for pediatric pads). A combination of postmarket experience data, relevant literature, clinical data, animal testing, and in-vitro bench testing has been reviewed to demonstrate a reasonable assurance of safety and effectiveness for the HeartStart Home and OnSite defibrillators.

## **II. INDICATIONS FOR USE**

The HeartStart OnSite (Model M5066A) is indicated for use on potential victims of cardiac arrest with the following symptoms:

- Unconsciousness; and
- Absence of normal breathing.

The HeartStart OnSite (Model M5066A) is indicated for adults over 55 pounds (25 kg). The OnSite is also indicated for infants/children under 55 lbs (25 kg) or 8 years old when

used with the optional infant/child SMART pads (Model M5072A). If Infant/Child SMART pads are not available, or you are uncertain of the child's age or weight, proceed with treatment using adult SMART pads (Model M5071A).

The HeartStart Home (Model M5068A) is indicated for use on potential victims of cardiac arrest with the following symptoms:

- Unconsciousness; and
- Absence of normal breathing.

The HeartStart Home (Model M5068A) is indicated for adults over 55 pounds (25 kg). The HeartStart Home is also indicated for infants and children under 55 lbs (25 kg) or 8 years old when used with the optional infant/child SMART pads (Model M5072A). If Infant/Child SMART pads are not available, or you are uncertain of the child's age or weight, proceed with treatment using adult SMART pads (Model M5071A).

### III. **CONTRAINDICATIONS**

The HeartStart Home and OnSite Defibrillators should not be used when a patient is conscious or breathing normally.

### IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the HeartStart OnSite Defibrillator Owner's Manual and the HeartStart Home Owner's Manual.

### V. **DEVICE DESCRIPTION**

The HeartStart Home (M5068A) and HeartStart OnSite (M5066A) Defibrillators are light-weight, easy-to-use AEDs, indicated to treat victims of sudden cardiac arrest (SCA). The OnSite model is intended for public access defibrillation and the Home model is intended for at home use.

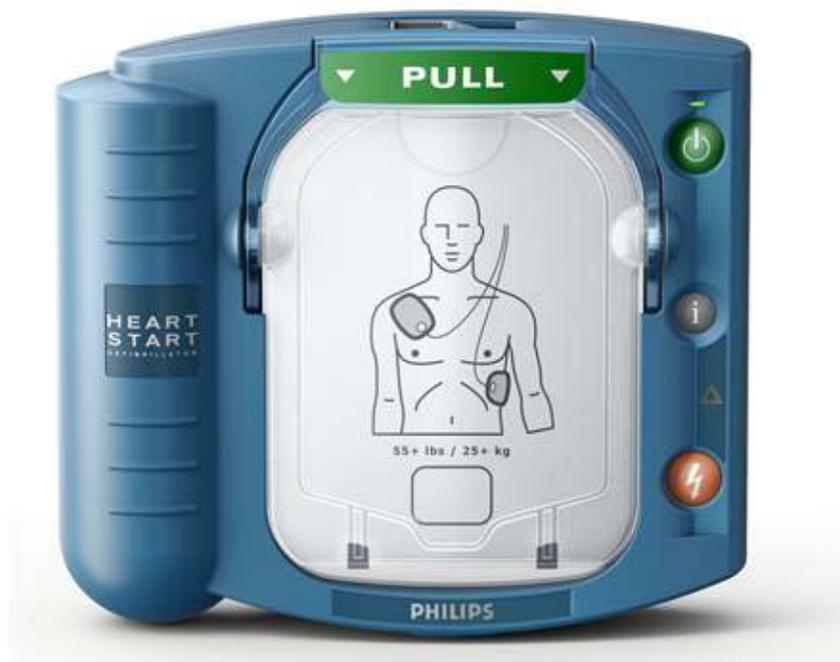
The Home and OnSite with the adult SMART pads cartridges (M5071A) are designated for over-the-counter sale; the infant/child SMART pads cartridge (M5072A) is prescription-use only. The Home and OnSite models are designed for use by a lay-person. The differences between the models of the devices pertain to the packaging and labeling, which reflects the different user environments. The Home model is indicated for at-home use and the OnSite model is indicated for public access defibrillation. Otherwise, the devices are identical.

The Home and OnSite prompts the user to take specific actions if a potentially shockable rhythm is detected. The Home and OnSite uses defibrillation pads placed on the victim's skin to deliver a shock. Once the defibrillation pads are placed on the patient, it analyzes the heart rhythm, determines whether or not a shock is required, charges the capacitor, and indicates to deliver a shock. The Home and OnSite are able to provide verbal

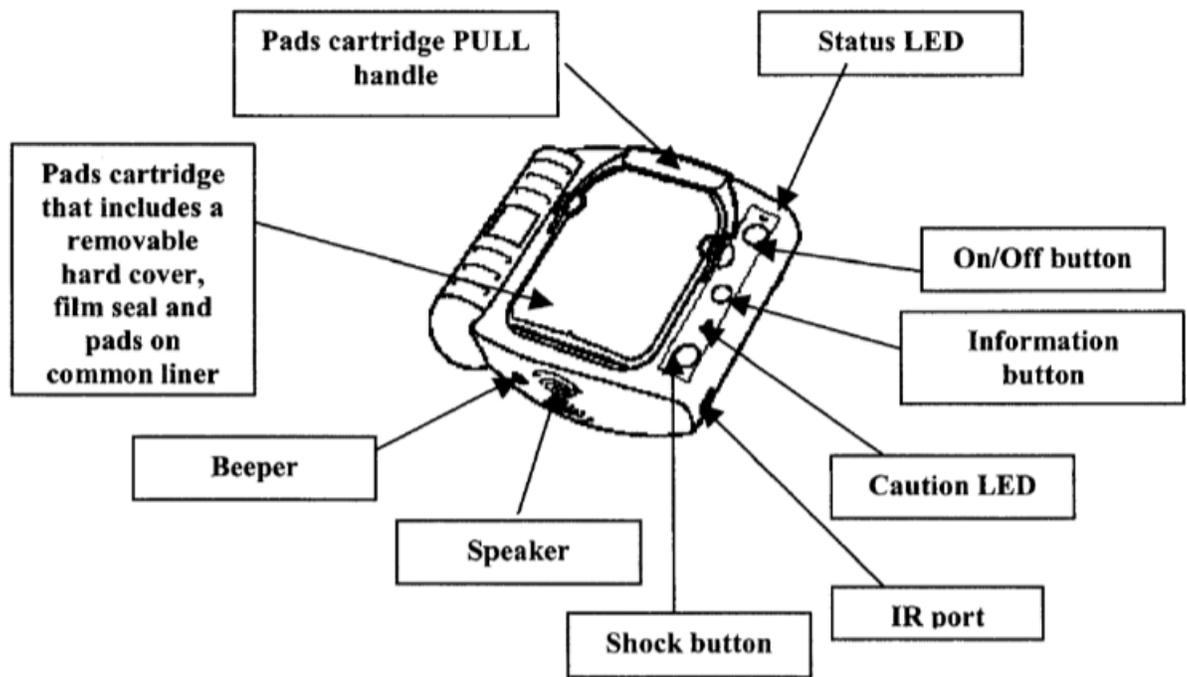
instructions to the user, detect where the user is in the event response, and provide general CPR coaching.

The HeartStart Home and HeartStart OnSite, which include the necessary accessories of a battery and SMART pads cartridge (adult and infant/child), use a proprietary shock advisory algorithm (Patient Analysis System [PAS]) and a truncated exponential biphasic shock waveform (impedance compensating SMART Biphasic waveform) to deliver a 150 J nominal shock to adults and 50 J nominal shock to pediatric patients to achieve its intended use.

Figure 1 shows an image of the Home and OnSite AEDs (which are the same device but for use in different settings). The AED features are identified in Figure 2.



**Figure 1: HeartStart OnSite and Home AED**



**Figure 2: HeartStart OnSite and Home Features**

**Readiness indicator LED (Status LED/Ready Light).** Used to indicate the device's status.

**On/off button.** A push button used to activate the device from stand-by mode or deactivate it to stand-by mode.

**Information button (i-button).** Used to provide information to the user. The information varies according to the state of the device when it is pushed.

**Caution LED.** The indicator blinks or is on when no one should be touching the patient, such as when ECG analysis is being performed or a shock is about to be delivered.

**Infrared (IR) port.** This port facilitates communication between the AED internal circuitry and external devices.

**Shock button.** Controls shock delivery. The button flashes when the AED is ready to deliver a shock.

**Speaker.** Voice instructions and information are provided through the speaker.

**Beeper.** The beeper provides chirps and warning tones.

**Pads Cartridge.** The cartridge stores the defibrillator pads in a sealed assembly until they are needed for use.

## **VI. ALTERNATIVE PRACTICES AND PROCEDURES**

Defibrillation is the only currently available treatment for termination of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). Over-the-counter defibrillation is designed to provide potentially lifesaving treatment prior to the arrival of emergency personnel, in the home or other areas without accessibility to a public access defibrillator.

## **VII. MARKETING HISTORY**

The Home AED was first marketed in the United States (US) in 2004 and is currently sold in Canada and the US. The OnSite AED was first marketed in 2002 and is currently sold in Australia, Canada, European Union countries requiring CE Mark, and over 40 countries in Central and South America, Asia, and Africa. These devices have not been withdrawn from marketing for any reason related to its safety or effectiveness.

## **VIII. PROBABLE ADVERSE EFFECTS OF THE DEVICE ON HEALTH**

Below is a list of the probable adverse effects (e.g., complications) associated with the use of the device.

- Failure to identify shockable arrhythmia;
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury;
- Inappropriate energy, 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 VF or cardiac arrest;
- Bystander shock from patient contact during defibrillation shock;
- Interaction with pacemakers;
- Skin burns around the defibrillation pads placement area;
- Allergic dermatitis due to sensitivity to the materials used in the defibrillation pads construction; and
- Minor skin rash.

## **IX. SUMMARY OF NONCLINICAL STUDIES**

### **A. Laboratory Studies**

The OnSite and Home AEDs and accessories underwent laboratory-based studies that included bench testing (summarized in Table 1), biocompatibility evaluations, electrical and EMC testing, and software verification and validation. Testing was conducted on key device subassemblies and the complete systems.

*Bench Testing*

**Table 1. Bench Tests**

<b>Test</b>	<b>Purpose</b>	<b>Acceptance Criteria</b>	<b>Results</b>
<b>Sealing/Moisture Resistance</b>	Verify the device meets the requirements for IPX1 rating.	The device shall be splash resistant per EN60529 Class IPx1.	Pass
<b>Mechanical Crush</b>	Verify the device continues to meet all performance requirements after receiving a 200 lb. load distributed across the AED.	The device shall comply with all of its performance requirements following application of a 90 kg (200 lb.) load distributed across 65+/-6.5 square cm. (10+/- square inches) to any location on its top surface.	Pass
<b>Dielectric Withstand – Operator Access</b>	Verify the device complies with the requirements of 60601-2-4 Edition 3.0 section 201.8.8.3 test 1.	The device shall comply with the requirements of 60601-2-4 Edition 3.0 section 201.8.8.3 test 1 when 3000V DC is applied between the patient end of the electrode cable with the electrodes shorted together and metal foil in intimate contact with non-conductive parts liable to be handled in NORMAL USE.	Pass
<b>Dielectric Withstand – Between Defibrillator Electrodes</b>	Verify the device complies with the requirements of IEC60601-2-4 Edition 3.0 section 201.8.8.3 test 2.	The device shall comply with the requirements of IEC60601-2-4 Edition 3.0 section 201.8.8.3 test 2 when 3000V DC is applied between the defibrillator electrodes.	Pass
<b>Dielectric Withstand – Across Defibrillator Switches</b>	Verify the device complies with the requirements of IEC60601-2-4 Edition 3.0 section 201.8.8.3 test 3.	The device shall comply with the requirements of IEC60601-2-4 Edition 3.0 section 201.8.8.3 test 3 when 3000V DC is applied across each switching device.	Pass
<b>Drop Test</b>	Verify the device complies with IEC 60601-1-11 and IEC 60601-1:15.3.4.2.	The device shall withstand a drop from 5 cm onto a 50 mm thick hardwood board over concrete on each of its three (3) axes without producing a safety risk.	Pass
<b>Therapy Delivery Endurance</b>	Verify the device complies with IEC 60601-2-4: *103 Endurance and IEC 60601-2-4:201.103 * Endurance.	The therapy delivery subsystem shall meet all of its performance requirements after being charged and discharged no less than 2500 times at rated energy into a 50 Ω load.	Pass

<b>Test</b>	<b>Purpose</b>	<b>Acceptance Criteria</b>	<b>Results</b>
<b>Primary Battery Stand-By Life</b>	Verify the installed primary battery will last a minimum of 3 years.	After being installed into a device kept in standby mode for the periods specified below, the primary battery shall be able to supply power according to specification “Low Battery, Remaining Capacity.” Typical: 4 years, assumes new battery, device with typical standby and self-test currents Minimum: 3 years	Pass
<b>Infant/Child Cartridge Identification</b>	Verify the insertion of the infant/child cartridge is identified.	The insertion of the infant/child cartridge initiates the pediatric mode of the device.	Pass

*Biocompatibility*

The Home and OnSite AEDs are not intended to be patient contacting, but the pads will contact the patient. Biocompatibility testing was performed per ISO 10993-5:2009 and ISO 10993-10:2010 for the adult SMART Pads cartridge and the infant/child SMART Pads cartridge. All testing was performed under GLP conditions utilizing Cytotoxicity and Sensitization protocols. All tests passed for biocompatibility.

*Electrical Safety and EMC*

The Home and OnSite AED hardware was validated and found to meet the performance criteria in the following standards (Table 2):

**Table 2. Electrical Safety and EMC Standards for Home and OnSite**

<b>ES60601-1:2005/(R)2012 And A1:2012</b>	C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
<b>IEC 60601-2-4: 2010 (Third Edition) for use in conjunction with IEC 60601-1 (2005)</b>	Medical electrical equipment Part 2: Particular requirements for the safety of cardiac defibrillators
<b>IEC 60601-1-2 Edition 4.0: 2014-02</b>	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
<b>IEC 60601-1-11 Edition 2.0 2015-01</b>	Medical Electrical Equipment -- Part 1-11: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Requirements For Medical Electrical Equipment

*Software Testing*

The software for the Home and OnSite AEDs was verified/validated and documented as a Major Level of Concern device according to the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The documentation included level of concern, software description, device hazard analysis, software requirements specification, software architecture diagrams, software design specifications, requirements traceability matrix, software development environment description, verification and validation documentation, revision level history, report of unresolved anomalies, and cybersecurity documentation, as applicable. Unit, integration, and system-level testing were documented and demonstrated that the software for the Home and OnSite AEDs performs as intended.

**B. Animal Studies**

The animal studies summarized in Table 3 were conducted in support of the adult and pediatric biphasic waveforms used with the OnSite and Home AEDs.

**Table 3. Animal Studies on Waveform**

<b>Study</b>	<b>Reference</b>	<b>Study Summary</b>
Comparison of biphasic to monophasic defibrillation in swine	1. Gliner et al. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. <i>Circulation</i> 1995, 92(6):1634-1643.	Three (3) interrelated studies were performed to evaluate the transthoracic defibrillation effectiveness of two (2) biphasic waveforms in comparison to monophasic shocks in 19 swine. The study demonstrated the superiority of truncated biphasic waveforms over monophasic waveforms for transthoracic defibrillation of swine.
Energy attenuation for pediatric AED treatment	2. Jorgenson D et al. Energy attenuator for pediatric application of an automated external defibrillator. <i>Critical care medicine</i> 2002, 30(Suppl):S145-147.  3. Tang W et al. Fixed-energy biphasic waveform defibrillation in a pediatric model of cardiac arrest and	An animal study was conducted on 29 swine to evaluate 50 J fixed-energy, impedance-compensating, biphasic truncated exponential (ICBTE) shocks. In the first experiment, four (4) different weight groups (3.8, 7.5, 15, and 25 kg) of piglets were induced to VF and defibrillated with a modified AED designed to deliver 50 J shocks. In the second experiment, three (3) weight groups of three (3) piglets each were induced to VF and resuscitated using an adult AED with pediatric pads. All piglets were resuscitated and total energy delivered was not weight dependent.

	resuscitation. Critical care medicine 2002, 30:2736-2741.	
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Tang et al.<sup>3</sup> conducted an evaluation of a 50 J biphasic waveform in a porcine model to determine if 50 J was an appropriate energy level (Phase 1), and then to evaluate the implementation of reducing the adult dose to the pediatric dose by means of an attenuated pediatric pads (Phase 2).

In Phase 1 of the Tang et al. study, four (4) groups of five (5) anesthetized mechanically ventilated piglets weighing 3.8, 7.5, 15, and 25 kg were evaluated for a total of 20 animals. Ventricular fibrillation was induced with an AC current delivered to the right ventricular endocardium. After 7 minutes of untreated VF, defibrillations were attempted with an impedance-compensated biphasic waveform defibrillator modified to deliver shocks with a nominal energy level of 50 J.

In Phase 2 of the study, shocks were delivered through special pediatric pads in conjunction with a conventional adult AED (FR2; Philips Medical Systems). The same VF induction and resuscitation protocol as Phase 1 was exercised on three (3) piglets in three (3) weight groups (3.7, 13.5, and 24.2 kg). The SMART biphasic waveform as implemented in the FR2 used in this study supports the SMART biphasic waveform as implemented on the OnSite and Home AED.

In both phases, all animals were successfully resuscitated. The average total number of shocks and total delivered energy was not weight dependent ( $p < 0.05$ ). Post-resuscitation hemodynamic and myocardial function quickly returned to baseline values in both experimental groups; 100% of the animals survived. Animals were monitored for survival at 24, 48, and 72 hours in Phase 1 and in Phase 2 for 4 hours; all animals survived through the last time-point.

### **C. Additional Studies**

#### *Shock Advisory Algorithm Validation*

The Patient Analysis System (PAS) shock advisory algorithm used in OnSite and Home was validated using ECG Databases intended to provide a representative sample of rhythms from patients who were in-hospital, out of hospital, with and without emergency care. The rhythms represented cardiac states ranging from normal sinus rhythms (NSR) to cardiac arrest. Data sources were the Massachusetts Institute of Technology-Beth Israel Hospital (MIT-BIH) Arrhythmia Database, MIT-BIH Malignant Ventricular Arrhythmia Database, MIT-BIH Supraventricular Arrhythmia Database, Creighton University Ventricular Tachyarrhythmia Database, American Heart Association ECG Database, Ohio State-Michigan Instruments Database, Philadelphia Heart Institute Database, Arntz Database, and the Heartstream Gemini II External Defibrillator Study Database.

The device meets the recommendations of the AHA for performance goals of arrhythmia analysis algorithms, as summarized in the Table 4 Shock Advisory Algorithm Performance.

**Table 4. Shock Advisory Algorithm Performance**

<b>Rhythms</b>	<b>Test Sample Size (Minimum Required)</b>	<b>Performance Goal</b>	<b>Observed Performance<sup>1</sup></b>	<b>90% One-sided LCL (Minimum LCL)</b>
<b>Shockable</b>				
Coarse Ventricular Fibrillation	300 (200)	>90% sensitivity	98.7%	97.3% (87%)
Ventricular Tachycardia (poly/flutter)	100 (50)	>75% sensitivity	78%	71.7% (67%)
<b>Non-shockable: minimum 300 total</b>				
Normal Sinus Rhythm	300 (100)	>99% specificity	100%	99.2% (97%)
Atrial Fibrillation, Sinus Bradycardia, Supraventricular Tachycardia, heart block, idioventricular, Premature Ventricular Contraction, Bundle Branch Block	450 (30)	>95% specificity	100%	99.49% (88%)
Asystole	100 (100)	>95% specificity	100%	97.7 (92%)

<b>Intermediate</b>	<b>Test Sample Size (Minimum Required)</b>	<b>Specificity Results<sup>2</sup></b>	<b>Sensitivity Results<sup>2</sup></b>	<b>Physician Disagreement<sup>3</sup></b>
VF (low rate/ amplitude)	100 (25)	(3/3) 100%	(52/97) 56.3%	17%
VT (unspecified)	115 (25)	(58/60) 96.7%	(13/55) 23.6%	71%

<sup>1</sup>These results are scored against a unanimous consensus from all three (3) physicians as to the recommended shock/no-shock response. Performance goals, minimum sample size, and minimum LCL were established by the AHA Scientific Statement (external reference 1).

<sup>2</sup>These result are scored against the majority recommendation from at least two (2) out of three (3) physicians as to the recommended shock/no-shock response.

<sup>3</sup>Physician Disagreement: this percentage represents the percentage of data files that generated a disagreement among the three (3) annotating physicians as to the recommended shock/no-shock response (i.e., the cases where a unanimous consensus was not obtained).

#### *Usability Studies*

A number of usability studies have been performed on the Home and Onsite AEDs to demonstrate the AED's usability in the indicated lay-user population and in home setting (for the Home AED).

## **X. SUMMARY OF PRIMARY CLINICAL STUDIES**

Philips, or its predecessor Heartstream, was directly responsible for the conduct of clinical trials related to the safety and effectiveness of the Philips family of AEDs. One of these trials, the Gemini Trial, had a feasibility study (Gemini I), a pivotal study (Gemini II), and a safety substudy. All trials were conducted under local investigational review board (IRB) or ethics committee approval and oversight.

**Table 5. Summary of Clinical Studies**

<b>Study Name</b>	<b>Reference</b>	<b>Study Summary</b>
<b>Gemini I Feasibility Study</b>	4. Bardy et al. Truncated biphasic pulses for transthoracic defibrillation. Circulation 1995, 91(6):1768-1774.	Randomized, controlled trial (RCT), single-center, 30 patients. Feasibility study to evaluate the effectiveness of two (2) different low-energy (115 J and 130 J), biphasic, truncated waveforms compared to a standard, damped sine waveform for transthoracic defibrillation. The biphasic truncated transthoracic shocks of low energy (115 J and 130 J) were as effective in the tested group as 200 J damped sine wave shocks used in transthoracic

		defibrillators.
<b>Gemini II Pivotal Study</b>	5. Bardy GH et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. <i>Circulation</i> 1996, 94(10):2507-2514.	RCT, 14 sites (US, CAN), 318 patients (electrophysiology laboratory). Low-energy truncated biphasic and high-energy damped sine monophasic were “not significantly different.” This study of a 115 J and 130 J biphasic waveform contributed to the development of the 150 J, nominal, shock energy that is used in the Philips AEDs.
<b>Gemini II Safety Substudy</b>	6. Reddy RK et al. Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock. <i>Annals of emergency medicine</i> 1997, 30(2):127-134.	Prospective, randomized, single-center sub-study, 30 patients. Twelve (12)-lead ECGs were collected from the patients that received either monophasic or biphasic defibrillation shocks. Independent, blinded clinicians determined the presence and severity of any ST-segment changes, a surrogate marker of cardiac injury. The high-energy monophasic waveform was associated with significantly more post-shock ST-segment changes on ECG than either of the two (2) biphasic waveform, suggesting that the biphasic waveform had a lower preponderance to cause cardiac injury.
<b>ORCA Trial</b>	7. Schneider T et al. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. <i>Circulation</i> 2000, 102(15):1780-1787.	European RCT at four (4) Emergency Medical Centers in 338 patients (115 patients with VF and emergency resuscitation). Study demonstrated superior defibrillation performance of the low-energy, impedance-compensating, biphasic waveform (SMART waveform) in comparison with escalating, high-energy, monophasic shocks in out-of-hospital cardiac arrest (average time from call to first shock was 8.9 minutes). SMART biphasic waveform defibrillated at higher rates than monophasic truncated exponential and monophasic damped sine (96% first-shock effectiveness vs. 59%), with more patients achieving return of spontaneous circulation (ROSC). Survivors of SMART Biphasic resuscitation were more likely to have good cerebral performance at discharge, and none had coma (vs. 21% for monophasic survivors).
<b>Pediatric AED Trial</b>	8. Atkins DL and Jorgenson DB. Attenuated pediatric	Prospective surveillance study analyzed pediatric patients (age 0-23 years, median 2) who had been treated with an AED with attenuated, lower energy

	electrode pads for automated external defibrillator use in children. <i>Resuscitation</i> 2005, 66(1):31-37.	pads. There were 26 confirmed pediatric-use cases, 23 of which could be analyzed. VF was reported and shocks were delivered in seven (7) cases with successful termination. Of the seven (7), five (5) survived to hospital discharge. In the 16 patients without VF, the device appropriately detected the rhythm as non-shockable and appropriately withheld shock delivery.
<b>OTC Home Use AED Trial</b>	9. Jorgenson DB, Yount TB, White RD, Liu PY, Eisenberg MS, Becker LB: Impacting sudden cardiac arrest in the home: a safety and effectiveness study of privately-owned AEDs. <i>Resuscitation</i> 2013, 84(2):149-153.	Retrospective surveillance study. Data were collected from cases of AED use through annual surveys, follow-up phone calls, media reports, and queries of supplies orders. Eighteen (18) OTC uses were reported that resulted in pads being applied to an adult patient in SCA. Of the cases, two (2) were pediatrics cases. SCA was witnessed in 76% of cases. In 56% of the cases, VF was the presenting rhythm and at least one shock was successfully delivered; 43% required two (2) or more shocks. Of the witnessed SCA, 67% survived to hospital discharge.

#### **A. Adult Defibrillation Waveform**

The pivotal clinical trial supporting the Philips SMART biphasic waveform was comprised of three (3) studies. The first was a single center feasibility trial (Gemini I), followed by a prospective randomized clinical trial (Gemini II), and finally a safety sub-study (Gemini Safety). These studies supported the safety and effectiveness of the SMART Biphasic defibrillation waveform.

##### 1. *Gemini I Feasibility Study*<sup>4</sup>

**Objective:** Gemini I was a clinical evaluation of the transthoracic defibrillation effectiveness of two (2) different biphasic truncated exponential waveforms (115 J and 130 J), with that of a then standard 200 J monophasic damped sine waveform.

**Study Design:** The study was a single site, prospective, randomized and blinded study involving patients undergoing transvenous implantable cardioverter defibrillator (ICD) surgery. Transthoracic ventricular defibrillation rescue shocks were tested after a failed transvenous defibrillation shock was delivered in the course of ICD testing. Each of the three (3) different rescue shocks was tested in random order in each patient. All shocks were delivered at end expiration. The shock was considered a success if it defibrillated a patient. The biphasic waveforms were generated using a custom, experimental defibrillation (Heartstream) system. The damped sine wave was from the Physio-Control Lifepak 6s defibrillator.

Results: Thirty-three (33) patients were enrolled and 30 completed the protocol. Of the 30 patients, 22 were men. All were undergoing a planned procedure for ICD implantation and consented to inclusion in the clinical study. All three (3) waveforms were equally effective at 97%, with 1 patient failing to be defibrillated with each waveform. The defibrillation data are shown below in Table 6.

**Table 6. Delivered Waveform Variables**

<b>Waveform</b>	<b>Energy, J</b>	<b>Current, A*</b>	<b>Voltage, V*</b>	<b>Duration, ms**</b>	<b>Resistance</b>
Standard	212 ± 6 (196-222)	33.8 ± 5.2 (23.7-44.9)	2497 ± 175 (2067-2842)	6.1 ± 1.0 (4.5-8.5)	76 ± 17 (46-120)
Biphasic Energy (J)	113 ± 2 (110-116)	25.1 ± 5.7 (14.9-39.5)	1857 ± 14 (1816-1885)	8.3 ± 0.4 (8.0-9.9)	78 ± 18 (46-127)
Biphasic Energy (J)	126 ± 3 (118-130)	21.9 ± 5.1 (13.6-34.4)	1611 ± 13 (1583-1637)	12.0 ± 0.0 (11.9-12.1)	78 ± 18 (46-120)
P, ANOVA	<.0001	<.0001	<.0001	<.0001	NS

Values are mean = SD and range.

\*Leading edge for biphasic waveform: peak for standard waveforms.

\*\*Sum of the durations of first and second phases for biphasic waveforms: durations after decay to 20% of peak for standard waveforms.

The defibrillation energy for the two (2) biphasic waveforms was significantly lower as compared to the damped sine wave ( $p < 0.001$ ), as was the peak current and voltage.

Conclusion: The results showed that biphasic truncated transthoracic shocks of low energy (115 J and 130 J) were as effective in the tested group as 200 J damped sine wave shocks used in standard transthoracic defibrillators.

## 2. *Gemini II Pivotal Study*<sup>5</sup>

Objective: The objective of this randomized, controlled, multi-center trial was to evaluate the safety and effectiveness of the investigational biphasic truncated exponential waveform vs. the control monophasic damped sinusoidal waveform from standard commercially marketed external defibrillators.

Study Design: The study was a prospective, randomized, double-blinded investigation conducted at 14 sites in the US and Canada. The study population consisted of 318 patients undergoing testing for insertion of an implantable defibrillator or follow-up electrophysiological evaluation post-implantation. As part of the normal testing protocol for ICDs, one or more transthoracic rescue shocks were delivered if the internal defibrillation attempt was not successful. In this study rescue shocks of investigational biphasic waveforms of 115 J and 130 J were compared to monophasic waveforms of 200 J and 360 J.

Results: A total of 318 patients were enrolled in the study, and after exclusion

criteria were applied there were 294 patients included in the study analyses, for a total of 513 shocks delivered during the study. Overall, for the 294 included patients analyzed, 513 transthoracic defibrillation attempts (shocks) were performed. The overall breakdown by waveform and success rates is as follows in Table 7 below.

**Table 7. Successful Defibrillations by Waveform Type**

<b>Waveform</b>	<b>Successful Defibrillation N (%)</b>	<b>95% Confidence Interval (%)</b>
<b>115 J Biphasic</b>	86 (89)	82-95
<b>130 J Biphasic</b>	144 (86)	82-95
<b>200 J Damped Sine</b>	143 (86)	81-91
<b>360 J Damped Sine</b>	80 (96)	92-100

Conclusion: For the primary hypothesis, the effectiveness of 130 J truncated biphasic waveform and 200 J monophasic waveform were not significantly different using the Pearson chi-square test ( $p = 0.97$ ). There were no statistically significant differences among the four waveforms with respect to defibrillation effectiveness. The 115 J and 130 J biphasic waveforms both demonstrate transthoracic defibrillation effectiveness equivalent to either the 200 J or 360 J monophasic waveforms.

The energy dose increased to 150 J in later clinical studies (ORCA study by Schneider<sup>7</sup>), and 150 J is the energy dose in the SMART biphasic waveform used in the Home and OnSite AEDs.

### 3. *Gemini II Safety Sub-Study*<sup>6</sup>

A single center, prospective analysis was conducted to look at potential differences in ECG ST-segment changes when comparing the waveforms from the pivotal trial. In this study the ST-segment changes were used as a surrogate for myocardial injury. Each patient received two (2) low-energy biphasic waveform shocks at 115 J and 130 J and a 200 J monophasic shock. ECGs were reviewed by two (2) blinded, independent reviewers.

A total of 30 patients, undergoing ICD implantation, were consented and enrolled. This 30 patient sub-study showed that ST-segment elevation was significantly greater for the 200 J damped sine wave ( $p < 0.001$ ), indicating a potential safety advantage associated with the biphasic waveform.

## **B. ORCA (Out of Hospital Response to Cardiac Arrest) Trial**<sup>7</sup>

This postmarket study supports the safe and effective use of the HeartStart Home and OnSite AEDs in out-of-hospital defibrillation. The ForeRunner device used in this study, and the Home and OnSite devices subject to PMA, both use SMART biphasic waveforms and PAS shock advisory algorithm technology.

Study Design: Four (4) European Emergency Medical Systems (EMS) located in Mainz, Germany, Hamburg, Germany, Brugge, Belgium, and Helsinki, Finland participated in the study. Patients were prospectively enrolled in the four (4) European EMS systems and included a total of 338 patients. First responders, including physicians in mobile intensive care units, paramedics, and emergency medical technicians used either impedance-compensated biphasic waveform AEDs (Philips ForeRunner 150 J) or monophasic damped sine (MDS) and monophasic truncated exponential (MTE) AEDs with an escalating energy protocol on victims of sudden collapse when defibrillator application was indicated.

The biphasic AEDs (ForeRunner) delivered 150 J impedance-compensated biphasic waveforms. The monophasic AEDs delivered either MTE or MDS defibrillation waveforms, depending on each investigational site.

If the responder suspected that the patient was in cardiac arrest, a sequence of up to three (3) defibrillation shocks was delivered. For monophasic AEDs, the shock sequence was 200 J, 200 J, then 360 J. For the biphasic AEDs, there was a single energy output of 150 J for all shocks.

Results: A total of 338 patients were enrolled. After exclusion criteria were applied, 115 patients were included in the principal analyses, 54 treated with biphasic and 61 with monophasic AED shocks. No significant differences were observed between the groups for mean age, sex, weight, primary structural heart disease, cause of cardiac arrest, by whom arrest witnessed, or duration of CPR.

Fifty-three (53) of 54 (98%) VF patients were defibrillated using 150 J biphasic shocks compared with 42 of 61 (69%) with 200-360 J monophasic shocks ( $p < 0.0001$ ). Further, all patients treated with biphasic AEDs were defibrillated with biphasic AEDs under EMS care, while this was not true for those treated with monophasic AEDs or a combination of monophasic AEDs and backup manual monophasic defibrillators (100% compared with 84%,  $p = 0.0025$ ). The impedance-corrected biphasic truncated exponential (ICBTE) waveform (SMART biphasic waveform) was more effective than the MDS waveform (98% vs. 77%, Fisher's exact test  $p = 0.02$ ). Further, more patients were defibrillated with the initial biphasic shock than with the initial monophasic shock (96% compared with 59%,  $p < 0.0001$ ). A higher percentage of patients (76%) achieved ROSC following 150 J biphasic waveform defibrillation compared with higher energy monophasic waveform defibrillation (54%) ( $p = 0.01$ ).

Conclusion: The high defibrillation effectiveness of the 150 J impedance-compensating biphasic waveform observed in this study was consistent with the Gemini I and II studies and strengthened the safety and effectiveness evidence base by providing randomized data from out-of-hospital emergency care. The concurrent controls substantiated the magnitude of the improvement in defibrillation effectiveness obtained with this biphasic waveform compared with conventional escalating-energy monophasic-waveform methods. The 150 J biphasic waveform defibrillated at higher rates, resulting in more patients who achieved ROSC. Although survival rates to

hospital admission and discharge did not differ, discharged patients who had been resuscitated with biphasic shocks were more likely to have good cerebral performance. In summary, the study demonstrated that an appropriately dosed low-energy impedance-compensating biphasic waveform (identical to the OnSite and Home waveform) strategy results in superior defibrillation performance when compared with escalating, high-energy monophasic shocks in out-of-hospital cardiac arrest.

### **C. Pediatric Defibrillation**

Pediatric defibrillation is supported in this submission with an animal study<sup>3</sup> (discussed in the Pre-Clinical section above) for the biphasic waveform energy of 50 J and a postmarket surveillance study for Pediatric AED use<sup>8</sup>.

#### *Postmarket Surveillance Study of Pediatric AED Use<sup>8</sup>*

The objective of the post-market surveillance study was to confirm that certain adult AEDs with shock intensity attenuation could be used safely and effectively in the pediatric population. The study population was infants and children less than 8 years of age or under 55 lbs. The HeartStart FR2 Defibrillator is a predecessor to the HeartStart OnSite and Home Defibrillators. Data from these defibrillators are applicable to the safety and effectiveness of the HeartStart OnSite and Home Defibrillators.

Study Design: This prospective, observational, post-market surveillance study included the Philips FR2 AED and Pediatric Attenuated Electrodes and the HeartStart OnSite AED with attenuation pads cartridge. Data from the FR2 are applicable to the consideration of the safety and effectiveness of the OnSite and Home AEDs because the OnSite and Home AEDs use the same principles for its SMART biphasic therapy waveform and PAS patient analysis algorithm.

Results: Through September 2004, there were 26 confirmed pediatric-use cases: 25 uses of the FR2 and 1 use of the OnSite. There were 18 US uses and eight (8) uses outside the US. There were 12 males, 11 females, and in three (3) cases the gender was not reported. The median age was 2 years. The users were predominately EMS personnel or health care professionals (n=24). Most arrests occurred at home (n=16).

Most patients to whom the device was applied had non-shockable rhythms (16, of which 13 were confirmed with AED data). Of seven (7) patients who had VF and received attenuated shocks, all had termination of VF and five (5) survived to hospital discharge. The median age of the seven (7) patients was 3 years (range 18 months to 10 years). These patients received on average two (2) shocks (range 1-4).

Conclusion: Based on the post market surveillance data available at time of study closure, the FR2 AED used with the FR2 infant/child attenuated pads and the HeartStart OnSite AED used with infant/child pads cartridge performed safely and

effectively in the pediatric population, which can be applied to the pediatric use of the HeartStart Home device.

#### **D. OTC Home Use**

The Philips HeartStart Home OTC defibrillator was cleared following the Circulatory System Devices Panel held on July 29, 2004, which was held to discuss the removal of the prescription requirement for the Home AED. After clearance, FDA issued a 522 Mandatory Post Market Study order for the Philips HeartStart Home Over-the-Counter study to discuss removal of the prescription requirement for the AED.

##### *Home Use AED Post Market Study<sup>9</sup>*

Objective: The 522 Post Market Study was an observational, post-market study to monitor and learn more about the use of defibrillators in the home, with no hypothesis testing or calculated sample size criteria. This study collected information from owners of HeartStart Home AED who purchased between November 2002 and December 2009.

Study Design: The methods used for obtaining information on home AED uses included surveying AED owners, identifying and contacting care providers, and subsequently completing detailed interviews of the care providers. The interviews sought to obtain information on any safety issues that arose during a use including harm to the patient, caregiver, or bystanders. The interviews allowed the user to describe the use in his/her own words as well as asked some specific questions regarding device use.

Data Collection: This study collected cumulative information from HeartStart Home AED owners who purchased their device after November 2002 through December 31, 2009. Survey data were solicited from all owners, with a total of 23,480 surveys distributed and 13,328 responses obtained. Only users who purchased OTC devices (no prescription needed) were included in the dataset for analysis.

Results: A total of 23,480 surveys were distributed and 13,328 responses were received. Eighteen (18) OTC uses were reported that resulted in pads being applied to an adult patient in SCA (median age 66 years). There were additionally three (3) pediatric uses, despite the fact that the pediatric pad cartridge requires a prescription; these were excluded this analysis.

In 12/18 (67%) uses, the arrest was witnessed. In 10/18 (56%) of the uses the patient presented in VF/shockable rhythm and at least one shock was delivered, median 1.5 shocks per patient (range 1-5). Shock effectiveness was 100% (10/10) for termination of VF. Of those shocked, 8/10 (80%) had a witnessed arrest and 2/10 (20%) were unwitnessed. The patients with unwitnessed arrest who were shocked survived to hospital admission, but later died in hospital 2/2 (100%). Of the patients with a witnessed arrest who were shocked, 5/8 (63%) survived to hospital discharge. No relevant trend was observed comparing responders to non-responders.

Conclusion: No new safety or effectiveness issues were identified upon completion of the study. The ability of home users, some with minimal training or experience, to use an AED was demonstrated. In this report of OTC use of AEDs in the home, five (5) of 8 (63%) patients with a witnessed VF arrest survived to hospital discharge. The survival rate observed in this post market study, with an acknowledged limited number of patients, validates the ability of lay responders to successfully and safely use an AED to help those in sudden cardiac arrest. This study on the Heart Start Home OTC AED and its conclusions are relevant to a finding of safety and effectiveness for the OnSite AED since the devices are identical in their design.

**E. Pediatric Extrapolation**

In this premarket application, the applicant provided a postmarket surveillance study for pediatric AED use (Atkins et al<sup>8</sup>). In addition, the applicant also provided supporting animal data (Tang et al<sup>3</sup>) to further support the use of the pediatric waveform.

**F. Human Factors and Usability Studies**

<p><b>Liberty I, 2004</b></p>	<p>This usability testing was done in support of the OTC indication. It was designed to assess “successful use” of the OTC AED alone and compared to the Philips prescription-use FR2. The usability study included a 2x2 design: groups were divided into FR2 or Home and then randomized to either video-training or naïve uses. One hundred and thirty-two (132) volunteers were studied using the FR2 and 124 volunteers were studied with the Home. Usability was measured by a “successful use” defined as completing all five (5) usability tasks within 5 minutes.</p> <p>For both the FR2 group and the Home group, video-trained participants had success rates of 86% and 89% respectively. There was no significant difference in success rates for the video-trained versus naïve untrained Home users (89% versus 87%, p=0.79). The high rate of successful use of the Home AEDs with voice prompts alone as a guide supports the assertion that both the Home and OnSite (which is identical in its design to Home) are is well designed for OTC use.</p>
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<b>Liberty II, 2004</b>	<p>The purpose of the usability study was to evaluate labeling specific to the OTC device. Part I comprised of a written test designed to assess the participants' comprehension of one of four labeling items. Part II was a simulated rescue scenario performed by participants who completed Part I. Three hundred and fifty-three (353) participants were recruited for Part I and 190 from Part I were randomized to participate in Part II.</p> <p>In Part I, participants were able to answer more than 70% of comprehension questions correctly indicating that the labeling that covers set-up, training, use and maintenance was well understood. In Part II, simulated use, there were no instances of harm to the caregiver or interference with the defibrillator operation. Time-to-pad placement and time-to-shock delivery were similar to that reported in the Liberty I Usability and Safety study. The study concluded that the major labeling materials are well understood and that all uses of the Home were safe.</p>
<b>Wahoo, 2015</b>	<p>A usability study was completed to validate minor updates to the Home and OnSite product design. User interface usability validation included five (5) MERT (medical emergency response team) users responding to simulated SCA, and replacing the device battery and pads. No participants created clinically significant hazards and all participants successfully replaced the device battery and pads within 3 minutes of starting the test.</p>

**G. Financial Disclosure**

The Financial Disclosure by Clinical Investigators regulation (21 CFR 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. There were four (4) clinical studies relevant to support safety and effectiveness for the OnSite and Home AEDs.

The GEMINI II study had 12 clinical investigators who contributed data. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

The ORCA study was conducted prior to 1999 by HeartStream, Inc. Philips acted with due diligence to obtain financial disclosure information for this clinical study, but was unable to do so on the basis of the age of the studies.

The Pediatric HeartStart AED study had one external clinical investigator, who did not have disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

The OTC Home Use 522 postmarket surveillance study had one external clinical investigator who did not have disclosable financial interests/arrangements as defined in sections 54.2(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 on January 25, 2011 as part of the 515(i) process. The majority of the panel recommended that AEDs be regulated as Class III PMAs to have better oversight of device manufacturing and post-market performance.

## XII. **CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES**

### A. **Effectiveness Conclusions**

The effectiveness data provided for the Philips' HeartStart Home and OnSite AEDs was based on the analysis of the defibrillation waveform, the arrhythmia detection algorithm, and data collected from published literature.

The pivotal clinical study by Bardy et al.<sup>5</sup> for in-hospital defibrillation confirmed that both the 115 J and 130 J biphasic waveforms demonstrated transthoracic defibrillation effectiveness equivalence to either the 200 J or 360 J monophasic waveforms. The energy dose increased to 150 J in subsequent clinical studies and in the HeartStart Home and OnSite AEDs.<sup>7</sup> The clinical study by Schneider et al.<sup>6</sup> for out-of-hospital defibrillation showed that more patients were defibrillated with the initial biphasic shock (96%) than with the initial monophasic shock (59%) and a higher percentage of patients achieved restoration of spontaneous circulation after 150 J biphasic waveform defibrillation (76%) compared with higher energy monophasic waveform defibrillation (54%).

Pediatric defibrillation was supported by a prospective, randomized animal study by Tang, et al.<sup>3</sup> performed on swine with the biphasic waveform energy of 50 J and a post-market surveillance study for pediatric use by Atkins et al.<sup>6</sup>. The Tang study demonstrated that the 50 J shock had successful ROSC and survival, without different effects on hemodynamics despite the difference in body weight, in an animal model.

A second set of experiments delivered shocks through special pediatric pads in conjunction with a conventional adult AED.

The Atkins clinical study<sup>8</sup> sponsored by Philips confirmed that the Philips SMART defibrillation waveform with 50 J energy could be used safely and effectively in the pediatric population.

**B. Safety Conclusions**

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in a clinical studies conducted to support PMA approval as described above. The results from the nonclinical testing performed on the AEDs demonstrated appropriate electrical safety, electromagnetic compatibility, environmental conditions, biocompatibility, mechanical performance, and overall performance. The preclinical animal study demonstrated the superiority of truncated biphasic waveforms over truncated monophasic waveforms for transthoracic defibrillation of swine. The clinical data, including published clinical studies for in-hospital and out-of-hospital use, as well as pediatric use, and usability/human factor reports, further demonstrate the safety of the device.

**C. Benefit-Risk Determination**

The probable benefits of the OnSite AED and the Home AED are based on published literature and post-market clinical data collected after the device initially received 510(k) clearance, as described above. The benefit of early defibrillation therapy is survival of patients in cardiac arrest. AEDs are life-saving devices used in emergency situations. They have shown to have a high benefit for patients with underlying diseases that remain undetected until sudden cardiac arrest occurs. The benefit of early defibrillation is providing the sudden cardiac arrest victim a chance at surviving the arrest since the chances of surviving a sudden cardiac arrest decreases by 7-10% for each minute without defibrillation.<sup>10</sup> Sudden cardiac arrest is a leading cause of out of hospital death in the US, claiming approximately 326,000 lives each year, with only about a 10% survival rate.<sup>11</sup> Sudden cardiac arrest is the unexpected loss of the heart's ability to effectively pump blood to the body and the victim is unconscious and unresponsive. The most common rhythm of adult sudden cardiac arrest resulting in ventricular fibrillation<sup>12</sup> whereas for infants and children sudden cardiac arrest related to breathing is more common, although the importance of rapid AED deployment remains.<sup>13</sup> The role early defibrillation plays in adult and pediatric sudden cardiac arrest has been extensively documented<sup>14</sup> and access to an AED provides a sudden cardiac arrest victim a chance of surviving the event.

The magnitude of this benefit is either life or death. The published literature and post-market clinical data have 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 underlying etiology and, though valuable to the patient, is highly dependent on subsequent treatment of the underlying disease. Duration of effect of the treatment is not related to the device.

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 may survive a life threatening cardiac arrest situation and will be able to seek further treatment.

1. Patient Perspectives: This submission did not include specific information on patient perspectives for this device.

In conclusion, given the available information above, the data supports that for patients with VF and pulseless VT, ~~both~~ the two most common cause of sudden cardiac arrest, the probable benefits outweigh the probable risks.

**D. Overall Conclusions**

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**

CDRH issued an approval order on June 6, 2019. The final conditions of approval cited in the approval order are described below.

The applicant will 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. The number of replacement defibrillation pads and replacement batteries issued to customers domestically for all causes.
3. 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.
4. A listing of any safety alerts, technical service bulletins, user communications, or recalls for devices under this PMA.

In addition to the conditions of approval above, the firm has agreed to implement alternate controls to address violations of the current good manufacturing practice requirements of the Quality System regulations found at Title 21, Code of Federal Regulations, Part 820. Continued approval of P160029 is contingent on implementing the alternate controls and providing evidence of effective implementation. This variance is conditioned on Philips making timely progress to address – to the agency’s satisfaction –

the violations identified in previous and any further inspections covering the device under this PMA.

FDA entered a consent decree of permanent injunction with Philips on October 31, 2017 which listed violations observed during an inspection of the firm's manufacturing facility in Bothell, WA on February 18, 2015 through April 21, 2015. FDA subsequently approved a variance plan on May 23, 2019 that met the requirements set forth in Section 520(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. 820.1(e)(2).

#### 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.

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