SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Wearable Cardioverter Defibrillator

Device Trade Name: Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) ("Jewel"), Jewel P-WCD Firmware, Device Accessories Skin Preparation Kit, Placement Accessory, Device Removal Kit, Optional Software Accessories ES Mobile Application, ES Cloud, ES Report Generator, ES Clinical Portal

Device Procode: MVK

Applicant's Name and Address: Element Science Inc.
301 Chesapeake Drive
Redwood City, CA 94063

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P230022

Date of FDA Notice of Approval: April 30, 2025

II. INDICATIONS FOR USE

The Jewel WCD is indicated for patients 18 years of age and older who are at risk for Sudden Cardiac Arrest and are not candidates for or refuse an implantable defibrillator.

III. CONTRAINDICATIONS

DO NOT USE the Jewel on patients who have an active Implantable Cardioverter Defibrillator (ICD).

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Jewel WCD labeling.

V. DEVICE DESCRIPTION

The Jewel WCD is a Patch Wearable Cardioverter Defibrillators (P-WCDs) for patients who are at risk for sudden cardiac arrest (SCA). It monitors a patient's cardiac rhythm continuously, and in the event that a patient experiences an episode of life-threatening VT (greater than approximately 200 beats per minute) or VF, the Jewel is able to deliver a therapeutic shock to convert a patient's rhythm out of life-threatening VT or VF and return to organized rhythm. The system components are:

- Jewel (P-WCD) model ES-2
- Jewel Firmware
    - Complex Programmable Logic Device (CPLD software)
    - BLE Microcontroller (MCU)

ACCESSORIES
- Skin Preparation Kit
    - Hair Trimmer
    - Skin Preparation Mitt
- Placement Accessory
- Device Removal Kit
    - Adhesive remover
    - Dish
    - Removal Tool
    - Soap Packet
    - Sponge

OPTIONAL JEWEL SOFTWARE ACCESSORIES
- ES Mobile Application
- ES Cloud (Medical Device Data Systems (MDDS))
- ES Report Generator
- ES Clinical Portal (MDDS)

Throughout the wear period, the Jewel does not need to be removed for any typical activity, which ensures that the patient is protected continuously during common daily activities, including cardiac rehabilitation, showering, and sleeping. The wear time is up to 8 days.

Figure 1. Illustration of the Jewel ES-2 P-WCD System

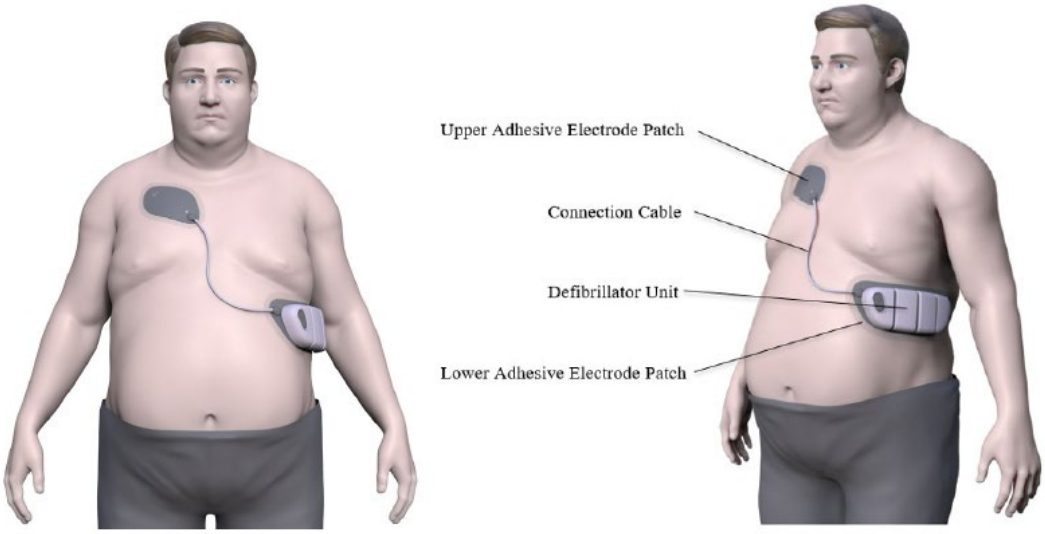

Figure 2. Jewel ES-2 P-WCD Applied to Patient's Torso

The ES-2 model of the Jewel is composed of four components: 1) an Upper Adhesive Electrode Patch; 2) a Lower Adhesive Electrode Patch with permanently attached Disposable Battery Unit; 3) a Connection Cable; and 4) a Reusable Defibrillator Unit. The Reusable Defibrillator Unit will remain with the subject for their entire prescription (40 to 90-days or longer), whereas the Disposable Upper Adhesive Electrode Patch and the Disposable Lower Adhesive Electrode Patch with permanently attached Disposable Battery Unit would only be used for a single wear (up to 8-days).

After each wear, the subject will remove the Disposable Upper and Lower Adhesive Electrode Patches (including used Disposable Battery Unit) from the Reusable Defibrillator Unit, and replace them with new Disposable Upper and Lower Adhesive Electrode Patches (including a new Disposable Battery Unit). The subject will be provided with multiple sets of new Disposable Upper and Lower Adhesive Electrode Patches (including new Disposable Battery Units) to ensure subjects are continuously protected throughout their prescription period.

Arrhythmia Detection and Shock Determination

The Jewel employs a proprietary algorithm to detect and classify ventricular fibrillation (VF) or ventricular tachycardia (VT) that is deemed to be life-threatening (shockable) versus cardiac rhythms that are non-life-threatening (non-shockable). The Jewel arrhythmia analysis algorithm works by making a binary decision (shockable or non-shockable) for several seconds of electrocardiogram (ECG) (called a "segment") collected on the Jewel. When a predetermined number of segments in a row are detected as shockable, the Jewel begins an alarm sequence, providing the user with an opportunity to defer the Jewel from delivering a shock. After an additional period of analysis to detect shockable rhythm, the Jewel waits an additional 8-seconds to ensure adequate time for a patient to defer a shock if needed, then delivers a shock to the patient if the shock is not deferred.

The arrhythmia detection algorithm uses a machine learning-based model to detect VT/VF.

Shock Waveform

The Jewel delivers the initial therapeutic shock with a fixed energy of 150 joules. The waveform is a Biphasic Truncated Exponential (BTE) defibrillation waveform using a constant energy pulse that is adjusted based on the transthoracic impedance (TTI) of the patient at the time of therapy delivery. Using a cardioversion algorithm, the Jewel will attempt to cardiovert the rhythm and synchronize the shock with the R-peak of the QRS complex. This automatic synchronization delivers a cardioversion shock to a patient if R-peaks are detected, suggesting that the rhythm is a life-threatening, fast VT. If the cardioversion algorithm is not able to identify a regular R-peak during the ventricular arrhythmia, the Jewel will deliver an asynchronous shock. After the initial therapeutic shock of 150 J, if the Jewel continues to detect a shockable rhythm, the Jewel will re-initiate the alarm sequence and continue to deliver a salvo of up to four (4) additional BTE shocks of 162 J, totaling five (5) consecutive shocks (150 J, 162 J,162 J,162 J,162 J).

In the event that the shockable rhythm is successfully converted to a non-shockable rhythm, the Jewel will 'reset' and continue monitoring for occurrence of a new shockable rhythm episode. If the patient experiences another episode of a shockable rhythm, the Jewel will continue to deliver additional salvos of shocks, each new salvo starting with an initial shock of 150 J followed by up to four (4) additional shocks of 162 J. The Jewel is able to deliver at least ten (10) shocks prior to provision of the Mandatory Replacement Alert (MRA), and will continue to deliver additional shocks as needed until battery power is exhausted.

Hardware, Software, and Accessories

The Connection Cable is a flexible, shielded multi-conductor cable assembly which traverses the torso and connects the Upper Adhesive Electrode Patch attached to the right upper chest to the Lower Adhesive Electrode Patch attached to the left lower torso. The Connection Cable is 16.5" in length.

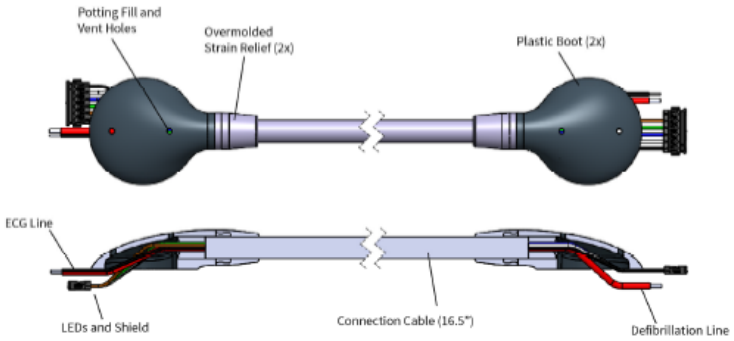

Figure 3. Connection Cable

Table 1 below lists the accessories that are included with the ES-2

Accessories	Description
70% IPA Mitt	Isopropyl Alcohol soaked fabric mitt used to clean the area of application on the patient's body prior to placing the ES-2 Device.
Foam Tool	Polyurethane Foam Tool swabs used to aid in removal of adhesive electrode patches
Silicone Adhesive Remover Solution (Off-shelf)	Used to aid in removal of residual adhesive material. This accessory is an off-the-shelf adhesive remover solution (Dow Corning® MG-2001 Silicone Blend).
Placement Accessory	Aids in the application of the ES-2 Device and ensures the Adhesive Electrode Patches are aligned correctly on the patient's torso.
Foam Sponge, Sterile	Used to remove remaining Adhesive Remover Solution and clean patient's skin prior to application of the ES-2 Device. This foam sponge is composed of reticulated medical foam, latex -free used in medical wipes, pre-operative skin preparation and medical swabs. SDP Foam Part Number: 22088A_Foam 90PPI Classification FDA- Product Code: GEC, Registered Establishment Number: 3012660022. Foam is 2"x3"x1"
Trimmer (Philips Norelco BG1026/60) (Off-shelf)	Used to trim excess torso hair prior to application of the ES-2 Device to the patient's skin
Skin Cleansing Solution (Coloplast Gentle Rain ® Extra Mild) (Off-shelf)	Used to clean the patient's skin prior to application of the ES-2 Device

Table 1. ES-2 Accessories

ES Mobile Application

The Element Science optional Mobile Application ("ES Mobile App") is an iPhone Operating System (iOS) mobile application that utilizes BLE (Bluetooth Low Energy) encrypted communication to retrieve status information from the Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) ("Jewel"). The optional ES Mobile Application does not allow the user to control or program the Jewel; but instead mirrors the device status communicated to the user by the Jewel's tri-color (red, yellow, green) LED lights, audio, and vibratory prompts. The ES Mobile Application consists of: Login Screen; Status Screens (which mirror the Jewel P-WCD's status); Help Section (which includes access to approved labeling); and User Settings Section.

ES Cloud

The Element Science optional ES Cloud is a collection of software and MDDS hardware infrastructure components that do not control or alter the functions or parameters of any connected medical devices, and:

- Provides authentication for the ES Mobile Application & other ES applications;

- Electronically transfers and stores patient medical device data from the Jewel P-WCD, and other data associated with a patient's record;
- Allows authorized users to view and download stored Therapy Report/s created by the ES Report Generator for patients who have received defibrillation therapy; and
- Provides business logic to Element Science personnel (such as device provisioning, tracking, and confirmation of Jewel serial numbers) to support the ES Mobile Application's functionality.

ES Report Generator
The Element Science optional ES Report Generator is a software component contained within the ES Cloud. The ES Report Generator software receives raw ECG Data from the Jewel via the optional ES Mobile Application and:

- Generates a Therapy Report which includes an ECG Printout;
- Stores the generated Therapy Reports securely in the ES Cloud; and
- Notifies the patient's Health Care Provider (HCP) about the availability of Therapy Report/s which can be accessed via the optional ES Clinical Portal.

ES Clinical Portal (MDDS)
The ES Clinical Portal within the ES Cloud allows Element Science authorized users to securely access and view patient data and Therapy Reports that are stored on the ES Cloud. The ES Clinical Portal also provides the ability for the clinicians to view, download, or print the Therapy Report/s for their patients if they choose to.

In addition to continuously monitoring for life-threatening VT or VF, the Jewel performs diagnostic checks periodically. As part of these checks, the Jewel evaluates if there are technical issues such as power interruptions, monitors the status of the battery, checks the sensing electrodes to determine contact with the body, and evaluates the degree of contact of the defibrillation electrodes with the user's body (contact integrity). The results of the periodic diagnostic checks may result in one of the following:

- Press Down Notification
- Elective Replacement Alert (ERA)
- Mandatory Replacement Alert – Medium (MRA-M)
- Mandatory Replacement Alert – High (MRA-H)

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle. The alternatives include:

- *Antiarrhythmic medication for reduction or suppression of certain ventricular arrhythmias*. Some drugs such as amiodarone and beta-blockers have been shown to decrease the number of ventricular arrhythmias, but not to reduce the incidence of sudden cardiac arrest. Additionally, antiarrhythmic medications can negatively impact morbidity and mortality.

- *Sudden Cardiac Arrest Treatment by Emergency Medical Services, EMS, or Calling 911*. Paramedics are trained to diagnose defibrillation-reversible conditions and apply such therapy if needed, but paramedics may not always be available in a timely manner to treat someone who suffers a cardiac arrest. Approximately 50% of cardiac arrests are unwitnessed.

- *Automatic External Defibrillators (AEDs) in the community*. Bystander use of an AED is an option; however, a bystander with an AED may not be available in a timely manner to treat a patient who suffers a cardiac arrest.

- *AEDs in the Home*. AEDs may be prescribed for use within the home, however, a caregiver in the home with an AED may not be available in a timely manner to treat a patient who suffers a cardiac arrest.

- *Implantable Cardioverter Defibrillators (ICDs)*. ICDs are surgically implanted in patients shown to have long term risk of SCA to protect them from sudden cardiac death. In general, patients having uncertain or temporary SCA risk are not indicated for ICD implantation. ICDs also impose risks of infection, inappropriate therapy, and require a waiting period during which the patient is vulnerable to a repeat cardiac arrest.

- *Telemetry monitoring within a Hospital Environment*. Hospitalization with telemetry monitoring for arrhythmias and rapid response for external defibrillation can be effective but requires extended hospitalization for monitoring and also attention by staff for arrhythmia notifications.

- *Use of other commercially available WCD products*.

VII. MARKETING HISTORY

The Jewel (P-WCD) 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 a Wearable Cardioverter Defibrillator.

- Failure to sense and detect a treatable ventricular arrhythmia resulting in death.
- Unsuccessful cardioversion or defibrillation resulting in death or disability.
- Inappropriate shock causing abnormal heart rhythms, including fatal arrhythmias.
- Improper, ineffective, or non-operation of the device due to external causes such as electromagnetic interference.
- Failure resulting from component failure.
- Damage to or reset of a pacemaker due to a shock.
- Superficial skin burns resulting from defibrillation.
- Pain from conscious shock.
- Mild to moderate skin irritation or allergic dermatitis due to sensitivity to the materials used in the construction of the adhesive electrode patches or Connection Cable.
- Mild to moderate skin irritation due to application and removal of the adhesive electrode patches.
- Skin infection (bacterial or yeast) secondary to continuous skin contact by the adhesive electrode patches or Connection Cable.
- Bystander shock from patient contact during a treatment event.
- Fire hazard in the presence of a high oxygen concentration.
- Muscle strain or discomfort.

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

IX. SUMMARY OF NON-CLINICAL STUDIES

A. Laboratory Studies

The Jewel system underwent laboratory-based testing that included bench testing summarized in Table 2 as well as biocompatibility evaluations, electrical and electromagnetic compatibility (EMC) testing, software verification and validation, arrhythmia detection validation, and human factors testing. Testing was conducted on key device subassemblies and the complete system.

Test	Purpose	Acceptance Criteria	Results
Accuracy of energy delivery	Verify the Jewel system energy delivery meets its specified requirements across a range of impedances.	The device shall meet or exceed the requirements of IEC 60601-2-4: 2010 clause 201.12.1 for delivered energy accuracy	Met

Test	Purpose	Acceptance Criteria	Results
Shock waveform verification study	Demonstrate shock waveform similarity to approved shock waveform	The shock waveform shall not deviate significantly from approved comparator device for peak current, peak voltage, phase duration, or tilt	Met
Control buttons qualifications	Verify reliability of the override button and LED subassembly	Deferral buttons shall be able to withstand 1,900 actuations without being damaged or losing functionality	Met
Electrode Patches and Connection Cable	Demonstrate that the Upper and Lower Patch and Connection Cable assembly meets ES-2 Device Requirement specification	Predefined design criteria for DC offset voltage, offset instability and noise, AC impedance, bias current, leadwire resistance, pull strength, flex circuit, and patch corrosion resistance	Met
Patch and Battery Unit	Demonstrate that the Adhesive Electrode Patches and Battery Unit meet device requirements and specifications	Predefined design criteria for battery voltage, patch attachment force, battery connection force, patch connection release, patch reliability, battery connector reliability, environmental integrity, and hardware corrosion resistance	Met
Subassembly Level Mechanical Testing	Demonstrate that the ES-2 Device meets mechanical requirements per the Product Requirement Specification	Predefined design criteria for battery hardware resistance, battery tab weld strength, pull strength, battery connector, flex circuit strength, water ingress protection, battery shelf life, and release liner pull strength	Met
Wear Life Device Performance (T=0)	Demonstrate that the ES-2 Device meets Wear Life Performance Mechanical requirements per the Product Requirement Specification	Predefined design criteria for patch long-term shear strength and ingress protection	Met
Mechanical Reliability	Demonstrate that the ES-2 meets the 6 month mechanical reliability requirements in the Hardware Requirements Specification	Predefined design criteria for flex circuit fatigue, compression cycling, and connectors reliability prior to defibrillation	Met
Device Drop Protection Test	Demonstrate that the ES-2 Device meets the Mechanical requirements per the Product Requirement Specification	Defined in IEC 60601-1 Clause 15.3.4.1 Drop Test for Body Worn Medical Electrical Equipment.	Met
Battery Qualification	Demonstrate that the Battery complies with the requirements of IEC 60086-4:2019 for Safety of Lithium Batteries	Per IEC 60086-4	Met
Wireless Coexistence	Demonstrate ability of system to withstand expected levels of wireless transmission from external sources	No observations at the applied levels and no latent effects resulting from exposure – system must operate as specified	Met

Test	Purpose	Acceptance Criteria	Results
High Voltage Capacitor Qualification	Demonstrate that the High Voltage Capacitor meets and exceeds the service life characteristic specified in the Product Requirements Specification	Meet predefined device performance criteria after 800 charge/discharge cycles at 50 degrees C	Met
Electrical Assembly, Low Voltage Testing	Demonstrate that the electrical assembly meets the low voltage requirements in the Electrical Hardware Requirements Specification and Product Requirements Specification	Predefined hardware functionality (e.g., button input, speakers, etc.) with 4.5V supply and ECG functionality to predefined specifications	Met
Electrical Assembly Overvoltage Protection Requirement	Demonstrate that the electrical assembly meets the overvoltage protection requirement	The hardware shall have overvoltage protection circuit that can be adjusted to a value greater than 790V	Met
Electrical Assembly, High Voltage Testing	Demonstrate that the electrical assembly meets the high voltage requirements in the Device Electrical Hardware Requirements Specification	Meet predefined functionality requirements for: internal discharge circuit, ECG signal acquisition accuracy, transthoracic impedance (TTI) measurement accuracy, full voltage charge measurement, printed circuit board assembly (PCBA) reliability, and capacitor accuracy	Met
Delivery of 20 High Voltage Shocks	Demonstrate that the device with a new and fully charged battery is capable of providing at least 20 maximum energy discharges at the maximum delivered energy under specified environmental conditions within 1,300 seconds	Clause 201.102.3.2 of IEC 60601-2-4	Met
8-Day Shock Test	Demonstrate that the device has sufficient battery capacity to function at the end of the intended wear period (8 days)	Deliver at least 10 shocks after simulated 8 day wear period.	Met
Commercial Air Travel Testing	Demonstrate that the Final Finished Form of the device is suitable for use in commercial aviation	RTCA DO-160G	Met
Shock and Vibration Testing for commercial air travel	Demonstrate that the device can withstand the mechanical stresses experienced during normal operating conditions in an aircraft	IEC 60601-1-12, Section 10.1.4, Requirements for Mechanical Strength for ME EQUIPMENT Intended for Airborne Use	Met
Mechanical Subassembly Level Testing (T=6-Months)	Demonstrate Subassembly performance following climatic conditioning and accelerated aging for 6 months	Predefined design criteria for battery hardware resistance, battery tab weld strength, pull strength, battery connector, flex circuit strength, water ingress protection, battery shelf life, and release liner pull strength	Met

Test	Purpose	Acceptance Criteria	Results
Patch and Battery Unit (T=6-Months)	Demonstrate that the Adhesive Electrode Patches and Battery Unit meet device requirements and specifications following climactic conditioning, shipping and distribution, and accelerated aging.	Predefined design criteria for DC offset voltage, offset instability and noise, AC impedance, bias current, leadwire resistance, pull strength, flex circuit, and patch corrosion resistance	Met
Release Liner Adhesion Testing (T=6-Months)	Demonstrate that the Patch Release Liners meets requirements after accelerated aging.	The average adhesive strength to Stainless Steel Patches, as tested per PSTC-101F, Peel Adhesion of Pressure Sensitive Tape, shall not decrease by more than 30% after environmental and shelf life conditioning. The adhesive strength between the Patches and Release Liner, as tested per ASTM D1876, (T-Peel Test), shall be less than or equal to 2 lb/in.	Met

Table 2. Testing Summary for the Jewel System

Biocompatibility Testing

Biocompatibility evaluation of the following components was performed in accordance with the recommendations of CDRH's biocompatibility guidance document, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within a risk management process":

- Upper Adhesive Electrode Patch,
- Lower Adhesive Patch with Defibrillator Unit
- Connection Cable
- Accessories:
    - IPA Mitt, Foam Tool
    - Placement Accessory
    - Foam Sponge
    - Silicone Adhesive Remover Solution
    - Trimmer
    - Skin Cleansing Solution

Direct patient contact materials underwent cytotoxicity, intracutaneous reactivity, and sensitization testing and were found to adequately demonstrate biocompatibility. Testing was conducted in conformance with the following standards:

- ISO 10993-1: 2018-08 Biological Evaluation of Medical Devices – Part 1 Evaluation & Testing within a risk management process

- ISO 10993-5: 2009/(R)2014 Biological Evaluation of Medical Devices – Part 5 Test for In Vitro Cytotoxicity
- ISO 10993-10: 2021 Biological Evaluation of Medical Devices – Part 10 Test for Skin Sensitization
- ISO 10993-12: 2021 Biological Evaluation of Medical Devices – Part 12 Sample Preparation and Reference Material
- ISO 10993-23: 2021 Biological Evaluation of Medical Devices – Part 23 Tests for Irritation

Given the prolonged nature of skin contact of the Electrode Patches as compared to traditional AEDs, additional biocompatibility endpoints were included in the clinical testing as discussed in Section X of this document.

Electrical Safety and EMC

Standards Testing included:

- IEC 60601-1: 2005, COR1:2006, COR2:2007, AMD1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 14971: 2019, Medical Devices – Application of Risk Management to Medical Devices
- EMC – IEC 60601-1-2: 2020-09, General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EMC – AIM 7351731, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers (RFID)
- IEC 62366-1: 2015, Medical Devices – Part 1 Application of Usability Engineering to Medical Devices
- IEC 60601-1-6: 2020, Medical electrical equipment – Part 1-6 General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-6: 2020-07, Medical electrical equipment – Part 1-8 General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-47: 2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC 60086-4: 2019-04 Primary batteries - Part 4: Safety of lithium batteries [Including: COR1 (2019) and COR2 (2020)]

Testing is Summarized in Tables 3 and 4 below.

Test Summary	Test Criteria or Applicable Standards	Result
Electromagnetic Immunity: Home Health Care Environment	IEC 60601-1-2 Ed 4.1	Pass
Electrostatic Discharge Immunity	IEC 60601-1-2 Ed 4.1	Pass
Electromagnetic Immunity: Security & Logistical Systems	N/A	Pass
Electromagnetic Immunity: Commercial Air Travel	RTCA DO-160G	Pass
Electromagnetic Immunity: Wireless Coexistence	ANSI C63.27-2017	Pass
Electromagnetic Immunity: RFID Exposure	AIM 7351731 Rev. 2	Pass
Electromagnetic Immunity: 5G & Wireless Power	The Jewel signal acquisition shall not be degraded by the presence of 5G devices or other wireless power sources	Pass

Table 3. EMC/EMI Performance

Standard	Description	AIM 7351731 Compliance Level	AIM 7351731 Test Level
IMMUNITY			
ISO 14223	Magnetic Field Immunity	134.2 kHz@65A/m	134.2 kHz@65A/m
IEC 14443-3 (Type A)	Magnetic Field Immunity	13.56 MHz@7.5A/m	13.56 MHz@7.5A/m
IEC 14443-4 (Type B)	Magnetic Field Immunity	13.56 MHz@7.5A/m	13.56 MHz@7.5A/m
IEC 15693; ISO 18000-3 Mode 1	Magnetic Field Immunity	13.56 MHz@5A/m	13.56 MHz@5A/m

ISO 18000-3 Mode 3	Magnetic Field Immunity	13.56 MHz@l2A/m	13.56 MHz@l2A/m
ISO 18000-7	Magnetic Field Immunity	433 MHz@3V/m	433 MHz@3V/m
ISO 18000-63 Type C	Radiated RF Immunity	860-960 MHz@54 V/m	860-960 MHz@54 V/m
ISO 18000-4 Mode 1	Radiated RF Immunity	2.45 GHz@54V/m	2.45 GHz@54V/m

Table 4. RFID Immunity

Due to the risk of EMI and EMD in railway environments [1], the Jewel system underwent the following additional EMC testing:

Railway Frequency	Frequency Range	Magnetic Field	Electric Field	Test Setup	Rhythm Samples	Test Result
25 Hz	22 – 28 Hz	70 A/m^2	1.2 kV/m Computational Analysis & Testing	Modified 1 kΩ load, parallel to 1 µF load in compliance with IEC 60601-2-4:2010/A01:2018, Clause 202.6.2.3.2	Jewel IDE Shockable Rhythms	PASS
60 Hz	57 – 63 Hz	70 A/m^2				PASS

Table 5. US Railway Immunity Testing (including frequency shifts and surrounding environments)

Packaging and Shelf Life

The packaging of the Jewel system was subject to and has met the requirements for international shipping and handling using procedures and methods defined in ISTA Procedure 3A, "Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs.) or less" as well as ASTM D4169-22, "Standard Practice for Performance Testing of Shipping Containers and Systems". All testing was conducted after accelerated 6-month aging according to ASTM F1980, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices". The shipping and storage temperature of the Jewel System is from -29°C to 60°C (-20°C to 140°F) with a relative humidity from 15% to 85%.

The shelf-life of the Jewel system is limited by the shelf-life of the Battery and Adhesive Electrode Pads. Testing has been completed that supports a shelf life of 6 months. The Jewel system may be stored at temperatures of 15ºC (59ºF) to 30ºC (86ºF) and from 5% to 95% humidity with no condensation.

Software

Comprehensive verification and validation testing were conducted to confirm that the software used in the Jewel WCD meets all specified requirements and that the software will operate reliably and safely under normal or abnormal use conditions.

The software for the Jewel WCD was presented to the FDA based on the Enhanced Documentation level according to the FDA Guidance Document, "Content of Premarket Submissions for Device Software Functions: Guidance for Industry and FDA Staff" issued on June 14, 2023. Software development activities included establishing detailed software requirements and design specifications, software code reviews, unit testing, system level testing, defect tracking, and dispositioning to ensure the software conforms to user needs and intended uses. Unit, integration, and system level testing was documented and demonstrated that the software for the Jewel WCD performs as intended.

Cybersecurity

A cybersecurity analysis was performed per the recommendations in the FDA guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical devices" (October 2, 2014), and the principles outlined in the FDA guidance for Industry and FDA Staff, "Postmarket Management of Cybersecurity in Medical Devices" (December 28, 2016).

B. Animal Studies

Element Science performed three (3) pre-clinical animal studies to test the safety and effectiveness of the Jewel system. The preclinical data were relied on to augment existing clinical evidence prior to initiation of the clinical trial. Consistent with prior defibrillation studies, swine were used as the animal model for these studies given their similarity to human thoracic anatomy, coronary arteries, and thoracic impedance. The pre-clinical studies were compliant with 21 CFR §58 Good Laboratory Practice for Nonclinical Laboratory Studies (GLP) Regulations. A summary of the porcine studies is provided below.

	GLP Safety and Efficacy Evaluation		**GLP Safety Evaluation**
Animal Model	Swine	Swine	Swine
Sample Size	N=4 test	N=7 test	N=3 test
Test Article	ES-1 Electrophysiology (EP) Lab System	ES-1 Wearable Cardioverter Defibrillator (WCD) Patch System ("ES-1 System")	Jewel EP Lab System
Methods	24 hours survival	Acute, non-survival	24 hours survival

Table 6. Summary of Animal Studies

Background: The initial GLP study included separate safety and performance arms treated as separate studies. The effectiveness arm was conducted to help establish defibrillation threshold/waveform shock success with the Jewel system applied at full energy. The safety arm was conducted to establish tissue safety with both 50% and full energy delivery. A second safety study was conducted to establish acceptable tissue injury associated with the Jewel. Results from the second GLP safety study established tissue safety with similarities in clinical pathology and histology outcomes for both test and control devices. Together with available clinical data, these two studies were found acceptable to support waveform safety and effectiveness for initiation of the pivotal trial.

Effectiveness Study

Objective: This acute, non-survival study evaluated the effectiveness of the Jewel system to detect ventricular fibrillation and/or rapid ventricular tachycardia, deliver defibrillation shocks, and terminate ventricular fibrillation.

Methods: Seven (7) animals underwent the "Defibrillation Detection/Treatment" procedure using the Jewel Patch Wearable Cardioverter Defibrillator. Each animal received between five (5) and twelve (12) shocks to evaluate the worst-case Jewel system use (delivery of up to two (2) salvos of up to five (5) consecutive defibrillation shocks).

Conclusion: Animals received between five (5) and twelve (12) shocks. Following this study, safety study 2, in addition to clinical data, were provided to demonstrate acceptable first shock success for the Jewel system under worst-case use conditions and clinical impedance ranges.

Safety Studies

Safety Study 1

Objective: This study was conducted to establish the tissue safety of the Jewel system as compared to a marketed control.

Methods: The GLP study was performed in a healthy porcine model. Two (2) animals received 5 defibrillation shocks each and two (2) additional animals received 10 defibrillation shocks each administered through the Jewel Electrophysiology Lab System. One (1) animal received 10 defibrillation shocks through a control comparator which was an FDA-approved AED. Clinical pathology was assessed at baseline, 6- and 24 hours post-treatment. Animals were euthanized approximately 24 hours post-procedure. Gross and histopathology of the tissue underlying the defibrillator pads was completed.

Conclusions: All animals survived to completion of the study. No adverse events were reported during treatments. Notable increases in creatine kinase (CK) and Troponin I (cTnI) as well as tissue injury on histology were addressed in a second safety study described below.

Safety Study 2
Objective: A second safety study was conducted to address tissue injury concerns following safety study 1. This study was conducted to establish tissue safety for the Jewel system as compared to a marketed control.

Methods: This GLP safety study was performed in a healthy porcine model. Three (3) animals received 10 defibrillation shocks each to simulate 2 complete salvos of 5 shocks administered through the Jewel Electrophysiology Lab System (initial shock – 150J and subsequent shocks of 162J). Three (3) additional animals received 10 defibrillation shocks each to simulate 2 complete salvos of 5 shocks administered through a control comparator which was an FDA-approved AED. Clinical pathology, including hematology, clinical chemistry, cardiac troponin I (cTnI), total creatine kinase (CK), CK-MB and CK-MM were measured at baseline, 6- and 24-hours post-treatment. Animals were euthanized approximately 24 hours post-procedure. Targeted necropsy and histologic assessment of the tissue underlying defibrillation pads was completed.

Conclusions: There was no significant difference in clinical pathology/cardiac biomarkers for the Jewel system and control groups. The gross and histologic injury to tissue deep to the Jewel system defibrillation pads showed that the Jewel system did not cause more injury than a marketed control device, establishing an expectation of tissue safety with worst-case clinical use of the system.

C. Additional Studies

Arrhythmia Detection Algorithm Validation
The VT/VF detector is an ML-based random forest algorithm used to decide whether a segment is shockable or non-shockable. The algorithm was trained and internally tested using a combination of public datasets and an Element Science's internal database. Demographic information for patient records in the ECG database is limited. The testing dataset used for final performance testing was collected independently from the training and internal testing datasets. It consisted of ECG samples recorded by the subject device and other similar AEDs equipped with multifunction electrodes in the same orientation as the Jewel device electrodes. The final performance testing utilizes only one record per person. The subject device met the performance goals established by the guidance from the American Heart Association (AHA) for arrythmia analysis algorithms [2] (see Table 7).

Rhythm		Element Science Sample Size (multi- function electrodes)	AHA Required Sample Size	AHA Performance Goal	Jewel Performance (Observed)	AHA 90% One-Sided Lower Confidence Limit Goal	Jewel Performance 90% One-sided Lower Confidence Limit	Results
Shockable	Coarse VF	203	200	> 90% Sensitivity	99.5% Sensitivity	>87% Sensitivity	97.8% Sensitivity	Pass
	Rapid VT	53	50	> 75% Sensitivity	100.0% Sensitivity	>67% Sensitivity	95.1% Sensitivity	Pass
	NSR	135	100	> 99% Specificity	100.0%	>97% Specificity	98.0% Specificity	Pass

Non-Shockable (306 Total)					Specificity			
	AF, SB, SVT, HB, IV, PVC	51	30	> 95% Specificity	100.0% Specificity	>88% Specificity	95.0% Specificity	Pass
	Asystole	100	100	> 95% Specificity	97.0% Specificity	>92% Specificity	92.7% Specificity	Pass
Intermediate	Fine VF	133	25	Report Only	100.0% Sensitivity	Not Required	Not Required	N/A (Report Only)
	Other VT	26	25	Report Only	100.0% Sensitivity	Not Required	Not Required	N/A (Report Only)
	Totals	701	530					

Table 7. Arrhythmia Detection Performance

Human Factors Testing

A human-factors/usability analysis was conducted in accordance with FDA's February 3, 2016 Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff" and IEC 62366-1:2015 - Medical devices - Part 1: Application of usability engineering to medical devices. It also complies with the FDA-recognized standard AAMI/ANSI HE75: 2009/(R)2018, Human Factors Engineering – Design of Medical Devices.

Each user group included at least 15 representative participants from the United States population.

- Patient (layperson) user group. Participants representing the patient (layperson) were healthy individuals from varied backgrounds who would be similar to the intended patient population with respect to demographics such as age, gender, body mass index (BMI), occupation, and education level.

- Bystander (layperson) user group. There are no specific demographics for a Bystander (Layperson) as anyone may encounter a patient wearing the Jewel. The goal was to enroll healthy individuals from varied backgrounds with respect to demographics such as age, gender, and occupation.

- Bystander (EMS Personnel) user group. Participants representing Bystander (EMS Personnel) had specific training in responding to medical emergencies. The goal was to enroll individuals from varied backgrounds who would have specific training with respect to Emergency Medical Services (EMS) occupations.

Critical Tasks have been identified through task analysis, Failure Mode Effects Analysis, identification of known use-related problems with similar devices, expert review, and formative evaluations of the Jewel.

A second study was performed with 15 patients to ensure that clinical users could successfully remove the device in an emergency without delaying medical intervention

such as imaging. Testing demonstrated that users could effectively use the labeling printed on the device to remove the Jewel with an average time of 6 minutes and 8 seconds.

The Jewel Human Factors (Usability) Study has been successfully conducted in accordance with IEC 62366-1:2015 and FDA's "Guidance for Applying Human Factors and Usability Engineering to Medical Devices," and has met the prespecified acceptance criteria for all Patient, Bystander, and Emergency Medical Services (EMS) User Groups.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The applicant performed two clinical studies to establish a reasonable assurance of safety and effectiveness of the Jewel Wearable Cardioverter Defibrillator for adult patients who are at risk for sudden cardiac arrest and who either are not candidates for or refuse an implantable defibrillator in the US (IDE) and outside the US (Electrophysiology laboratory ventricular fibrillation conversion study) under IDE # G180065. Data from these clinical studies were the basis for the PMA approval decision. Summaries of the clinical studies are presented below.

A. Study Design

Patients were treated between January 12, 2022 and July 31, 2023. The database for this PMA reflected data collected through July 31, 2023 and included 322 patients. There were 29 investigational sites.

The study was a non-randomized, uncontrolled, open-label, prospective, multicenter, pivotal clinical trial consisting of up to 370 subjects at 29 US sites. The study enrolled subjects diagnosed with a risk of SCA who were not candidates for or who refused an ICD and was evaluated for success based on an observed inappropriate shock rate of < 2.0 per 100 patient months and a clinically significant cutaneous Adverse Device Effect (ADE) of < 15%.

The initial sample size was calculated as a total of 290 subjects, with an estimated average wear time of 2.5 subject-months per subject, assuming an expected inappropriate shock rate of 0.37 per 100 subject-month. This would provide 98% power to demonstrate an inappropriate shock (IAS) rate < 2 per 100 subject months (assuming a Type I error rate of 0.02). A total of up to 370 subjects could be enrolled to account for withdrawals, patients lost to follow-up, and damaged devices. It was also expected that 3 successful shock events would occur during the course of the study.

A revised Statistical Analysis Plan (SAP) included an interim analysis at 179 or more subjects with analyzable wear time (> 14.1 hours per day) to allow for early stopping the trial for safety and effectiveness. The safety endpoint was to be tested at the interim time point only if the Primary Effectiveness Endpoint was achieved. The trial would only be stopped if both the Primary Safety and the Primary Effectiveness

Endpoint are achieved. A one-sided upper 97% confidence bound was used which effectively spent 0.03 alpha on the interim analysis (reserving 0.02 alpha for the final analysis). Sample size was driven by effectiveness (inappropriate shock rate). An early stopping point was approved by FDA after 179 subjects achieved analyzable wear time. Both an intent to treat (ITT) was performed for the 179 subjects, and a modified analysis using actual wear time instead of wear time as assumed by the prescription.

The primary effectiveness endpoint was the rate of inappropriate shock. A one-sided upper 98% confidence limit was to be calculated for the inappropriate shock rate per 100 patient-months at the final analysis.

Only first inappropriate shocks were to contribute to the analysis of this endpoint. All wear times through the first inappropriate shock or through death or withdrawal were to contribute to the Poisson regression model. All follow-up beyond the first inappropriate shock was not to be used.

The formal hypotheses were:
- H0: Inappropriate shock rate $\geq$ 2.0 per 100 patient-months
- Ha: Inappropriate shock rate < 2.0 per 100 patient-months

The statistical method used for testing the primary safety endpoint used a one-sided, exact 95% upper confidence bound which was compared to the performance goal of 15%. The exact confidence bound was constructed using the Clopper-Pearson method. The hypotheses tested was as follows:

$$H0: \pi \geq 0.15 \quad Ha: \pi < 0.15$$

where π is the observed proportion of subjects experiencing a clinically significant cutaneous adverse device effect.

An ADE was considered "clinically significant" if it resulted in the subject being permanently withdrawn from the clinical trial by the Investigator due to a skin event.

The secondary safety endpoint of successful conversion of a shockable rhythm was not formally tested.

The secondary endpoint to observe a compliance rate of subjects wearing the Jewel of greater than 14.1 average hours per day during a prescription wear period was calculated as follows:

> (Total prescription wear period – Sum of gaps between individual wears) / Total prescription wear time (expressed in days)

The prescription wear time was defined as 12-hours after the date and time the first Jewel which was applied to the subject's body transitions to Monitor Mode to the date and time that the last Jewel worn by the subject transitioned to Off Body Mode.

Periods of removal time as identified by timestamped transitions between modes, periods of removal time as attested to by a subject or health care provider and confirmed by electrocardiographic data, and periods of time in which there are missing data (e.g., due to unreturned or damaged devices) were excluded.

To calculate average hours per day, the gaps between individual device wears were summed and the total was subtracted from the total prescription wear time. That absolute device wear time was divided by the total prescription wear time to obtain the average.

Monitoring was provided through the Sponsor with on-site visits and centralized data review of case report forms (CRFs). All shocks during analyzable wear time, both appropriate and inappropriate, were to be reviewed and adjudicated by a Clinical Events Committee (CEC). The CEC was to meet regularly, and could meet on-demand, as needed. Safety oversight was provided under the direction of a Data Safety Monitoring Board (DSMB) composed of individuals with appropriate expertise, including electrophysiology. Members of the DSMB were independent from the study conduct and free of conflict of interest. The DSMB met to assess safety and study conduct and provide its input to the Sponsor. The DSMB operated under the rules of an approved charter that was written and reviewed at the organizational meeting of the DSMB.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the Jewel IDE study was limited to patients who met the following inclusion criteria.

   1. Patients of any gender aged ≥ 18 years.
   2. Patients with either:
      a. a measured LVEF lesser than or equal to 40% (as assessed by techniques such as, but not limited to, cardiac angiography, echocardiography, magnetic resonance imaging, or radionuclide angiography within the last 30 days prior to enrollment) AND identified as presenting with a diagnosis of an AMI, ischemic cardiomyopathy (includes congestive heart failure: New York Heart Association (NYHA) Class I – III), non-ischemic cardiomyopathy, or myocarditis;

         OR

      b. who had a temporary or long-term contraindication to receiving an ICD, who have had an ICD removed, or who refused an ICD

         OR

      c. whose ICD implantation was delayed due to COVID-19 infection or exposure-related risks.

Patients were not permitted to enroll in the Jewel IDE study if they met any of the following exclusion criteria:

1. Member of a vulnerable patient population as defined in ISO 14155;
2. Life expectancy of less than one year, including end-stage heart failure, cancer, or other diagnosed condition;
3. Patients with an anticipated initial prescription period over 180 days (limitation only to allow timely closure of this clinical trial);
4. Patients with an advanced directive prohibiting resuscitation;
5. Existing ICD;
6. Existing unipolar pacemaker;
7. Existing FDA-cleared or FDA-approved active implantable or body worn medical device(s) that the Sponsor required to be removed prior to the study but which could not be removed;
8. Clinically significant valve disease, including aortic stenosis, mitral stenosis; mitral regurgitation, tricuspid regurgitation, insufficiency of the aortic or pulmonary valves, any of which was likely to require surgery in the next year;
9. A planned procedure, such as Coronary Artery Bypass Graft, within six (6) months;
10. End-stage renal disease, or chronic renal failure requiring hemodialysis;
11. Planned discharge to an institutional setting with an anticipated stay of greater than seven (7) days;
12. Having a mental, visual, physical, or auditory deficit, that would impair their ability to properly place, remove, or interact with the Jewel System;
13. Unable to understand English for the purposes of interacting with the device;
14. Unable to use a wearable defibrillator due to physical conditions (bandages preventing electrode contact, physical deformities preventing electrode contact, etc.);
15. Dextrocardia;
16. Body circumference of less than 27 inches or greater than 56 inches in the intended area of the Belt component of the Placement Accessory;
17. Active skin breakdown, erythema, or other signs of infection in the pectoral or torso regions where the Adhesive Electrode Patches are applied;
18. Females who were pregnant or breast-feeding, or planning to be pregnant in the next 12 months;
19. No US-based postal address that can be used to ship and receive study devices and supplies (a Post Office box was not an acceptable address for product shipments).
20. Patients who, in the opinion of the Investigator, were anticipated to be non-compliant with study instructions;
21. Unable to provide or have diminished capacity to provide informed consent;
22. Any condition that an Investigator believed would interfere with the intent of the study or make participation not in the best interest of the patient.
23. Participation in an investigational study of a drug, biologic, or device not currently approved for marketing; or

24. Allergic to or have had a known adverse reaction to medical adhesives or hydrocolloids.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at screening, training and enrollment (Day 0), exchange 1-4, exchange 5 and end of prescription period, and study exit visit.

Evaluations included informed consent, demographics, medical history, weight, and eligibility review. Training and enrollment included training, accessory fitting, device application, photos, and quality of life assessment. Objective parameters measured during the study included wear experience questionnaire, occurrence of shocks, changes to medications or health status, and adverse event evaluation. Adverse events and complications were recorded at all visits.

The key timepoints are shown in Table 8 below.

Procedures	Screening	Training & Enrollment (Day 0)	Exchange 1 – Exchange 4	Exchange 5 – end of prescription period	Study Exit Visit (end of prescription period ± 14 days)
Informed consent	X				
Demographics	X				
Medical history	X				
Weight & measurements	X				
Eligibility review (Informed Consent/Ethics Commitee)	X				
Jewel training		X			
Placement Accessory fitting		X			
Apply device		X	X	X	
Photos of device after application		X	X (Optional)		
QOL questionnaire		X			X
Wear experience questionnaire			X		
Occurrence of any shocks/deferrals			X	X	X
Changes to medications, health status			X	X	X
Subject request(s) for assistance, training, or supplies			X	X	
Adverse Event evaluation			X	X	X
Exit Interview					X

Table 8. Study Schedule of Activities

3. Clinical Endpoints

   The per protocol safety analysis of clinically significant cutaneous ADE was performed on the 264 subjects who were enrolled for > 12 hours. Of these, 7 (2.65%, 95% CI 1.07-5.39%) reported a significant cutaneous ADE. This met the success criteria of < 15%.

   With regards to effectiveness, an ITT inappropriate shock rate was 0.357, with an Upper 98% CI of 1.526, which met the endpoint of < 2.0 per 100 patient-months, which was calculated using actual wear-time.

With regard to success/failure criteria, the study met its primary efficacy endpoint showing an inappropriate shock rate similar to another approved WCD (< 2 per 100 subject months) and safety endpoint (< 15%) with a low rate of serious cutaneous reactions.

B. Accountability of PMA Cohort

At the time of database lock, of 254 patients enrolled in the PMA study, 290 (90.06%) patients are available for analysis at the completion of the study.

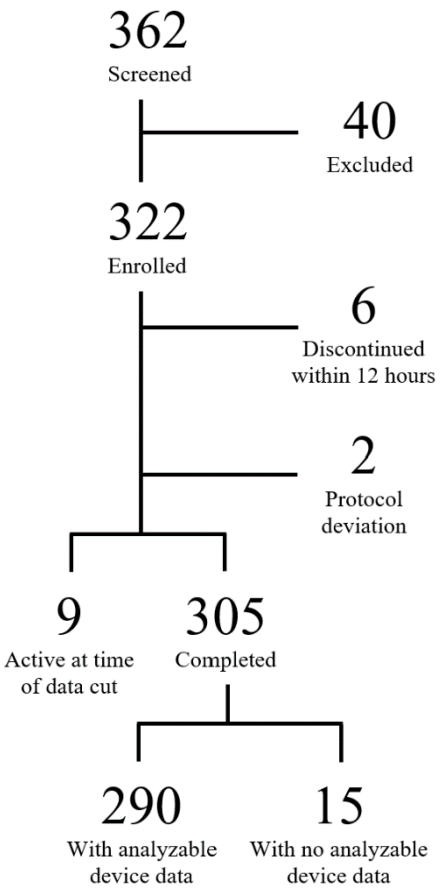

Figure 4. Representation of Subject Disposition

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a wearable cardioverter defibrillator study performed in the US.

Characteristic	Primary Safety Population (N=305)	Primary Analysis Population (N=290)
Age at Enrollment (Years)		
N	305	290
Mean ± SD	57.9 ± 13.3	58.6 ± 13.0
Median [Min, Max]	60.0 [21.8, 88.7]	60.3 [21.8, 88.7]
Sex, n (%)		
Female	92 (30.2%)	90 (31.0%)
Male	213 (69.8%)	200 (69.0%)
Ethnicity		
Hispanic or Latino	12 (3.9%)	10 (3.4%)
Not Hispanic or Latino	293 (96.1%)	280 (96.6%)
Race, n (%)		
White	220 (72.1%)	212 (73.1%)
Black or African American	74 (24.3%)	67 (23.1%)
Asian	4 (1.3%)	4 (1.4%)
American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
Native Hawaiian/Other Pacific Islander	0 (0.0%)	0 (0.0%)
Other	8 (2.6%)	8 (2.8%)
Body Mass Index (kg/m2)		
N	305	290
Mean ± SD	30.0 ± 6.7	30.0 ± 6.7
Median [Min, Max]	29.3 [15.3, 57.1]	29.3 [15.3, 57.1]
Systolic Blood Pressure (mmHg)		
N	303	288
Mean ± SD	117.4 ± 16.5	117.3 ± 16.5
Median [Min, Max]	115.0 [82.0, 174.0]	114.5 [82.0, 174.0]
Diastolic Blood Pressure (mmHg)		
N	303	288
Mean ± SD	71.7 ± 10.6	71.5 ± 10.6
Median [Min, Max]	70.0 [43.0, 105.0]	70.0 [43.0, 105.0]
Pulse (Beats/Min)		
N	303	288
Mean ± SD	79.3 ± 15.8	79.1 ± 15.5
Median [Min, Max]	78.0 [33.0, 144.0]	78.0 [33.0, 144.0]
Temperature (ºC)		
N	286	271
Mean ± SD	36.6 ± 0.3	36.6 ± 0.3

Median [Min, Max]	36.6 [34.8, 37.4]	36.6 [34.8, 37.4]
Respiration (Breaths/Min)		
N	297	282
Mean ± SD	17.4 ± 1.8	17.4 ± 1.8
Median [Min, Max]	18.0 [11.0, 28.0]	18.0 [11.0, 28.0]

Table 9. Data on Patient Demographics and Characteristics

Condition	**Primary Safety Population, n/N (%) (N=305)**	**Primary Analysis Population, n/N (%) (N=290)**
Prior myocardial infarction (MI)	97/303 (32.0%)	94/288 (32.6%)
Prior coronary artery bypass grafting (CABG)	35/303 (11.6%)	34/288 (11.8%)
Prior percutaneous coronary intervention (PCI)	113/303 (37.3%)	109/288 (37.8%)
Prior congestive heart failure (CHF)	221/303 (72.9%)	207/288 (71.9%)
NYHA Class		
Class I	13/227 (5.7%)	11/213 (5.2%)
Class II	80/227 (35.2%)	76/213 (35.7%)
Class III	67/227 (29.5%)	61/213 (28.6%)
Class IV	10/227 (4.4%)	9/213 (4.2%)
Not Applicable	57/227 (25.1%)	56/213 (26.3%)
History of Atrial Fibrillation	79/303 (26.1%)	76/288 (26.4%)
Type		
Persistent	17/77 (22.1%)	16/75 (21.3%)
Paroxysmal	60/77 (77.9%)	59/75 (78.7%)
Unstable Angina	38/297 (12.8%)	36/283 (12.7%)
Resolved	25/38 (65.8%)	24/36 (66.7%)
Ongoing	13/38 (34.2%)	12/36 (33.3%)
History of nonsustained ventricular tachycardia (NSVT)	60/303 (19.8%)	58/288 (20.1%)
Status		
Resolved	21/60 (35.0%)	20/58 (34.5%)
Ongoing	39/60 (65.0%)	38/58 (65.5%)
History of ventricular tachycardia (VT)	62/303 (20.5%)	62/288 (21.5%)
Status		
Resolved	24/62 (38.7%)	24/62 (38.7%)
Ongoing	38/62 (61.3%)	38/62 (61.3%)
History of Sudden Cardiac Arrest	28/303 (9.2%)	27/288 (9.4%)
Hypertension	216/303 (71.3%)	204/288 (70.8%)
Status		

Resolved	7/215 (3.3%)	6/203 (3.0%)
Ongoing	208/215 (96.7%)	197/203 (97.0%)
History of Smoking	139/303 (45.9%)	129/288 (44.8%)
Diabetes	103/303 (34.0%)	100/288 (34.7%)
Type		
Type 1	1/103 (1.0%)	1/100 (1.0%)
Type 2	102/103 (99.0%)	99/100 (99.0%)
COVID-19 Status		
Never Infected	151/303 (49.8%)	144/288 (50.0%)
Suspected Infected	10/303 (3.3%)	9/288 (3.1%)
Confirmed Infected	61/303 (20.1%)	60/288 (20.8%)
Vaccinated	152/303 (50.2%)	149/288 (51.7%)
Baseline Medications		
Angiotensin-Converting Enzyme Inhibitors (ACEi)/angiotensin II receptor blockers (ARB)/ angiotensin receptor/neprilysin inhibitor (ARNi)	202/287 (70.4%)	192/274 (70.1%)
Amiodarone	50/287 (17.4%)	48/274 (17.5%)
Other antiarrhythmic agent	4/287 (1.4%)	4/274 (1.5%)
Anticoagulant	91/287 (31.7%)	86/274 (31.4%)
Other antiplatelet agent	84/287 (29.3%)	82/274 (29.9%)
Aspirin	144/287 (50.2%)	141/274 (51.5%)
Beta blocker	233/287 (81.2%)	224/274 (81.8%)
Calcium channel blocker	24/287 (8.4%)	22/274 (8.0%)
Digoxin	5/287 (1.7%)	4/274 (1.5%)
Diuretic	136/287 (47.4%)	128/274 (46.7%)
Other lipid lowering agent	15/287 (5.2%)	15/274 (5.5%)
Mineralcorticoid receptor antagonist	112/287 (39.0%)	107/274 (39.1%)
SGLT2i	98/287 (34.1%)	93/274 (33.9%)
Statin	172/287 (59.9%)	168/274 (61.3%)

Table 10. Patient Medical History

Among the patients included in the safety analysis, 107 patients reported non-ischemic cardiomyopathy, 52 patients had ischemic cardiomyopathy, 80 patients reported a temporary contraindication to ICD, 1 patient had delayed ICD implant due to COVID-19, 5 patients had ICD removal, 4 patients had long term contraindication to ICD, 2 patient had myocarditis, 12 patients refused ICD, and 42 patients reported acute myocardial infarction. 195 patients had an anticipated prescription length of 90 days and 20 had a prescribed wear time of 40 days and 90 patients had other prescription wear time. The mean anticipated prescription length was 91.9 ± 37.8 days.

The demographic profile and ethnic/racial diversity is mostly male and white. The medical history and clinical comorbidities appear to well represent the kinds of patients for whom a wearable cardioverter defibrillator would be indicated.

D. Safety and Effectiveness Results

1. Safety Results

   The analysis of safety was based on the cohort of 305 subjects enrolled for > 12 hours. Of these, 7 (2.3%) reported a clinically significant cutaneous ADE. This met the success criteria of < 15%.

   The key safety outcomes, adverse events, and device deficiencies for this study are presented below in Tables 11 to 13.

Number of Patients with Clinically Significant Cutaneous ADEs (n/N)	% (95% Confidence Interval)	Upper Limit of One-Sided 98% CI	Endpoint Result
7/305	2.30 (0.93% - 4.67%)	4.80%	Success

Table 11. Clinically Significant Cutaneous ADEs

Adverse effects that occurred in the PMA clinical study:

Two deaths occurred after study exit; neither was adjudicated as due to the device.

There were a total of 155 device related adverse events (AEs) related to the device. 73 were resolved. 74 were ongoing and the status of 8 events were unknown at the time of the report. Of the 155 AEs, 110 were mild and the remaining were moderate. 25 of the device related AEs required medical treatment. For 72 of the AEs no action was taken.

ADE Category	*No. of ADEs*	*Mild ADE*		*Moderate ADE*		*Severe ADE*	
		Resulting in exit	Not resulting in exit	Resulting in exit	Not resulting in exit	Resulting in exit	Not resulting in exit
Rash[†]	108	8	62	15	23	0	0
Skin injury[‡]	14	0	13	0	1	0	0
Patient discomfort[§]	34	1	26	0	7	0	0
Device issue[*]	1	0	1	0	0	0	0

Table 12. Summary of ADEs stratified by type and severity

†Rash includes the following Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms: Dermatitis acneiform, application site erythema, application site rash, application site urticaria, application site vesicles, cellulitis, blister, erythema multiforme, medical device site rash, skin lesion, dermatitis, contact skin irritation, erythema, rash, rash erythematous, rash vesicular, urticaria
‡Skin injury includes the following MedDRA Preferred Terms: application site bruise, application site injury, application site laceration, skin disorder, skin exfoliation, skin hyperpigmentation, wound, skin erosion, contusion, skin injury
§Patient discomfort includes the following MedDRA Preferred Terms: application site burn, application site irritation, application site pain, application site pruritis, application site reaction, pruritis, medical device site pain, skin burning sensation, abdominal pain lower, tenderness, burning sensation, paresthesia, medical device site irritation
*Device issue includes the following MedDRA Preferred Terms: Device issue, Shock

There were a total of 84 device deficiencies reported during the study which are summarized in Table 13 below. There was one device deficiency that resulted in an adverse event when the device was removed.

Deficiency Category	Number of Subjects with Deficiency Type (N = 305 subjects)	Number of Deficiencies
A Part of Device Component is Broken	3 (1.0%)	3
Defibrillator Unit Housing Issue	11 (3.6%)	13
Device UI Not as Expected	11 (3.6%)	17
Other	24 (7.2%)	33
Patch Issue	12 (3.9%)	18

Table 13. Device Deficiencies

2. Effectiveness Results

The analysis of effectiveness was based on the 290 evaluable patients at the specified prescription wear times.

The inappropriate shock rates met the primary effectiveness endpoint of < 2.0 per 100 patient-months and is aligned with current standards of care.

Endpoint	Point Estimate	Upper One-Sided 98% Confidence Limit
Primary endpoint: Inappropriate shocks per 100 patient-months per study participation length	0.357	1.527
Primary endpoint: Inappropriate shocks per 100 patient-months using prescription length	0.226	0.967
VEST[3] results	0.372	0.724

Table 14. Primary Effectiveness Endpoint: Inappropriate Shock Rate

The primary efficacy outcome of inappropriate shock rate is similar to other approved wearable cardioverter defibrillator systems[3].

A total of nine (9) subjects each received one appropriate shock during the study period; eight (8) were successful and the unsuccessful shock was not repeated due to removal of the device and replacement with an external defibrillator per hospital protocol.

Of the 257 Visit 1 surveys entered, 30% (77/257) subjects reported overall satisfaction (No activities affected, no sensations on top or bottom patches). The number of surveys entered in following wears decreased; at visit 9, though only 18 subjects responded, overall satisfaction was reported by 38.9% (7/18) of patients

The mean wear time was over 21 hours a day. 91% of subjects wore the device for > 14 hours a day. The results from the quality of life surveys were unchanged throughout the course of the study.

3. Subgroup Analyses

No analyses were performed for sex-, gender-, age-, race-, or ethnicity-subgroups.

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

Electrophysiology Laboratory Conversion Study

The Jewel EP Lab Study was a non-randomized, uncontrolled, open-label, prospective study of a modified Jewel device designed to evaluate termination of acute induced episodes of ventricular tachycardia (VT) or ventricular fibrillation (VF) in the electrohysiology (EP) lab setting.

The planned maximum sample size of 24 subjects was based on a group sequential design measuring the observed proportion of successful life-threatening VT or VF terminations. The group sequential design used a Pocock alpha spending function and allowed for testing after 12 or 18 or 24 subjects were enrolled. In line with the Pocock alpha spending function, a one-sided lower 97.4% exact confidence bound was calculated using the exact binomial (Clopper-Pearson) method at each testing point. The sample size was driven by effectiveness.

Inclusion Criteria:
1. Subjects of both genders of at least 18 years of age.
2. Subjects who are scheduled for a standard EP clinical procedure where life-threatening VT or VF may spontaneously occur or may be induced.

Exclusion Criteria:
Candidates will be ineligible for enrollment if any of the following conditions apply:

1. Subjects who may require sterile access to the right upper pectoral or lower left torso regions during the planned EP procedure.
2. Subjects who have taken amiodarone in the past 3-months.
3. Subjects with an existing unipolar pacemaker.
4. Subjects who exhibit a Left Ventricular Ejection Fraction (LVEF) less than 20% (as assessed by techniques such as echocardiography, Magnetic Resonance Imaging, or radionuclide angiography) within the last 6-months.
5. Subjects who have been diagnosed with heart failure (Class IV) or experienced an acute heart failure exacerbation within the previous 30-days.
6. Subjects who exhibit unstable angina.
7. Subjects with atrial fibrillation with contraindication to anticoagulation or improper anticoagulation management.
8. Subjects who are participating in an investigational study of a drug, biologic, or device not currently approved for marketing.
9. Subjects who are allergic to or have had a known adverse reaction to medical adhesives.
10. Subjects who have active skin breakdown, erythema, or other signs of infection in the pectoral or torso regions where the study device is applied.
11. Subjects with a lower abdomen circumference of less than 68.5 cm or greater than 142 cm.
12. Females who are pregnant or breastfeeding or planning to be pregnant in the next 12-months.
13. Subjects who cannot provide or have diminished capacity to provide informed consent.
14. Any condition that an Investigator believes would interfere with the intent of the study or is not in the best interest of the patient.
15. Any patient that according to the Declaration of Helsinki is unsuitable for enrollment.

The primary endpoint was the percent of successful terminations of induced life-threatening VT or VF.

Success is defined if the lower confidence limit exceeds the Performance Goal of 62% using a one-sided lower 97.4% exact confidence bound at one of the three testing points. Successfully meeting the Performance Goal of observed first shock conversion success rates of >87.5% in the Jewel EP Lab Study.

Twenty subjects were consented and enrolled sequentially in this clinical investigation. Eighteen subjects were enrolled according to the Eligibility Criteria in the protocol and these subjects are included in the Per Protocol calculations. Of the 2 subjects who were incorrectly enrolled with existing Exclusion Criteria, one was withdrawn from the study, and one was treated. Both subjects were recorded as Protocol Deviations and therefore were not included in the Per Protocol analysis. The subjects were recovered following

normal hospital protocol. No additional clinical follow-up is required following the acute procedure per the protocol, as no adverse events were experienced by any subject.

Variable	All Enrolled Subjects, n = 20	Per Protocol Subject, n=18
Gender, male (% of total)	17/20 (85%)	15/18 (83%)
Average Age, years (range)	64.5 (28-80)	63.8 (28-80)
Race, white (% of total)	20/20 (100%)	5/5 (100%)
Average Height, cm (range)	177.4 (160-190)	176.8 (160-190)
Average Weight, kg (range)	89.6 (58-129)	88.9 (58-129)
Average BMI (range)	28.3 (20.2-36.9)	28.3 (20.2-36.9)
Average Ejection fraction, % (range)	34 (20-55)	34 (20-55)
Medical History	*N (%)*	*N (%)*
Recent myocardial infarction (% of total)	2/20 (10%)	2/18 (11%)
Recent coronary artery bypass graft (% of total)	0/20 (0%)	0/18 (0%)
Class IV chronic heart failure (% of total)	0/20 (0%)	0/18 (0%)
Sudden cardiac arrest (% of total)	3/20 (15%)	3/18 (17%)
Explants (% of total)	5/20 (25%)	5/18 (28%)
Hypertension (% of total)	12/20 (60%)	10/18 (56%)
History or current use of tobacco (% of total)	11/20 (55%)	11/18 (61%)
Non-sustained ventricular tachycardia (VT) (% of total)	1/20 (5%)	1/18 (6%)
VT (% of total)	3/20 (15%)	2/18 (11%)
Diabetes (% of total)	6/20 (30%)	5/18 (28%)
Atrial fibrillation (% of total)	3/20 (15%)	3/18 (17%)
Unstable angina (% of total)	0/20 (0%)	0/18 (0%)

Table 15. Demographics

The conversion rate was 88.9% (16/18) with a one-sided lower 97.4% exact confidence bound of approximately 65.4% which exceeded the 62% Performance Goal.

There were no subgroup analyses.

XI. 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. The pivotal clinical study included

30 investigators. 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.

XII. 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.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The primary effectiveness endpoint in the IDE study was defined as an observed inappropriate shock rate of no more than 2.0 inappropriate shocks per 100 patient-months using a one-sided upper 98% confidence interval and analysis of 290 completed patients with analyzable wear time. The inappropriate shock rate was calculated to be 0.357 shocks per 100 patient-months, with an upper 98% confidence interval of 1.526, meeting the primary effectiveness endpoint successfully.

A total of 9 appropriate shock events were observed with 8 successful single-shock conversions. The 8 successful shocks observed in the IDE study met the secondary effectiveness endpoint of observing at least one successful conversion of shockable rhythms.

The animal safety study demonstrated successful detection and treatment of induced VF in 7 animals which received between 5 and 12 shocks.

The effectiveness of the AI/ML-based rhythm recognition detection algorithm was established by meeting predefined objective performance criteria (Kerber et. al. [2]) for the correct detection of shockable and non-shockable rhythms. All records were collected from representative multifunction ECG electrodes placed in representative anatomical locations to the Jewel electrode orientation.

A total of 305 patients for whom wear data on Jewel P-WCD was available demonstrated wear compliance for an average daily wear time of 21.3 ± 4.48 per day (median 23.5, interquartile range: 20.7, 23.9), meeting the secondary effectiveness endpoint of observing an average wear duration of greater than 14.1 hours per day.

The effectiveness of the Jewel P-WCD is further established by the successful study results of the Jewel EP Lab study, in which the Jewel electrode patches and defibrillation waveform were demonstrated to successfully terminate life-threatening VT or VF with a single shock in 88.9% (16/18) cases.

The Human Factors study demonstrated that the Jewel system and its associated labeling could be understood by the intended users and is therefore effective for its intended users, use, and use environments, from a human factors standpoint.

B. Safety Conclusions

The risks of the device are based on animal studies as well as data collected in clinical studies conducted to support PMA approval as described above. Of the 305 patients included in the safety analysis population of the IDE study, 7 subjects reported a clinically significant cutaneous ADE. This result was well below the performance goal of 15% of patients experiencing a clinically significant cutaneous ADE resulting in a successful endpoint. A total of 176 adverse events were reported, of which 155 were noted as related to the device. There were no serious adverse events or deaths reported that were related to the device.

The 2 animal safety studies demonstrated that there is no significant difference in clinical pathology or cardiac biomarkers between the Jewel device and an FDA-approved comparator device. The gross and histologic injury deep to the Jewel system defibrillation electrodes is consistent with similar injury from the FDA-approved comparator device. Of the 7 animals in the study there was no significant difference in clinical pathology, including hematology, clinical chemistry, cardiac troponin I (cTnI), total creatine kinase (CK), CK-MB or CK-MM.

The safety of the device is further established by no adverse events or deaths reported in the Jewel EP Lab Study,

The successful results of the Human Factors study, demonstrate that clinicians can successfully remove the Jewel system in a timely manner for emergency interventions such as imaging.

Extensive non-clinical (bench) testing demonstrated that the design and construction of the device are sufficiently robust to withstand normal use as well as reasonably foreseeable misuse for the duration of the prescription wear period.

C. Benefit-Risk Determination

The probable benefits of the device are based on data collected in clinical studies, animal studies, and non-clinical studies to support PMA approval as described above. There is substantial evidence of benefit from electrical countershock for ventricular arrhythmias in the treatment of sudden cardiac arrest and the prevention of sudden

cardiac death. The probable benefit of protection from neurologic injury and death are more than minimal.

The probable risks of the device are also based on data collected in clinical studies conducted to support PMA approval as described above. The probable risks of the device are skin reaction, intolerability for the wearer, excess inappropriate alarms, inappropriate shock due to misclassification, failure to detect VT/VF, and ineffective shock resulting in death.

Additional factors to be considered in determining probable risks and benefits for the Jewel device included the uncertainty in ascertaining the rate of these risks due to the relatively small sample size and the rarity of arrhythmia events, even in a high risk population.

1. Patient Perspective
   Patient perspectives considered during the review included patient-reported outcomes on quality of life (QOL) while wearing the device. Validated measures of health-related QOL, the EQ-5D-3L and Visual Analogue Scale (VAS), were used in the Jewel IDE Study to quantify any impact that the Jewel P-WCD had on patient QOL. The absolute change between the second and first survey results for both EQ-5D-3L and VAS was small (0.04 ± 0.180 and 0.9 ± 19.85, respectively). Overall, the scores demonstrated that patients were in good health during the course of this study and the Jewel P-WCD did not impact their health and well-being negatively.

   In conclusion, given the available information above, the data support that for adult patients who are at risk for Sudden Cardiac Arrest and either are not candidates for or refuse an implantable defibrillator 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. Probable benefits are more than minimal. Probable risks appear to be the same or less than with other approved wearable cardioverter defibrillator devices. Considering the limited sample size, rarity of events, and use of AI/ML, a robust post market study is necessary to confirm performance.

XIV. CDRH DECISION

CDRH issued an approval order on April 30, 2025. The final clinical conditions of approval cited in the approval order are described below.

Conditions of Approval

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.

Post Approval Study

The Jewel P-WCD post approval study is intended to confirm the safety and effectiveness of the Jewel P-WCD in the post-market setting. This is a prospective observational study demonstrating the detection rate of the Jewel AI/ML-based Rhythm Recognition Detector. FDA suggests utilizing an objective performance goal with a minimum collection of 200 VT/VF events. No additional patient follow-up is required. In addition to the arrhythmia analysis performance, the PAS will also report the false alarm rate of the Jewel system with a percentage of false alarms which were successfully averted by the patient and those which resulted in an inappropriate shock to the patient. Lastly, the PAS will also report the rate of skin related adverse events by severity and whether the patient stopped using the Jewel due to skin related adverse events. This was reviewed under the protocol provided via email on April 10, 2025. Element Science 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 P230022.

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

XV. 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.

XVI. REFERENCES

[1] Final Report on Magnetic and Electric Field Testing of the Amtrak and Metro North Northeast Corridor and New Jersey Transit North Jersey Coast Line Rail Systems: Volume I – Anaysis. U.S. Department of Transportation, Federal Railroad Administration. 1993; Report Number DTFR53-91-C-00047.

[2] Kerber et. al, 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.

[3] Olgin JE, Pletcher MJ, Vittinghoff E, Wranicz J, Malik R, Morin DP, et al. Wearable Cardioverter–Defibrillator after Myocardial Infarction. *New England Journal of Medicine*. [Online] 2018;379(13): 1205–1215. Available from: doi:10.1056/NEJMoa1800781.