SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Extravascular Implantable Cardioverter Defibrillator (EV-ICD) and Extravascular Lead
Device Trade Name:	Aurora EV-ICD™ System This system is comprised of the following: • Aurora EV-ICD™ MRI SureScan™ DVEA3E4 Extravascular Implantable Cardioverter Defibrillator (EV-ICD) • Aurora EV-ICD Application Software SW041 v8.4 • Epsila EV™ MRI SureScan™ EV2401 Extravascular lead • Epsila EV™ EAZ101 Sternal Tunneling Tool • Epsila EV™ EAZ201 Transverse Tunneling Tool
Device Procode:	LWS, NVY
Applicant's Name and Address:	Medtronic, Inc. Cardiac Rhythm Management 8200 Coral Sea Street NE MV MVS11 Mounds View, MN 55112
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P220012
Date of FDA Notice of Approval:	October 20, 2023

II. INDICATIONS FOR USE

The Aurora EV-ICD MRI SureScan Model DVEA3E4 device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies. Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include:

- Previous ventricular tachyarrhythmias
- Coronary disease with left ventricular dysfunction
- Cardiomyopathy
- Inherited primary arrhythmia syndromes
- Congenital heart disease

Note: For patient-specific recommendations regarding indications for primary and secondary prevention of sudden cardiac death, refer to current clinical guidelines from the European Society of Cardiology (ESC), American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society (HRS).

The Epsila EV™ MRI SureScan™ Model EV2401 extravascular lead is indicated for use in the anterior mediastinum for pacing therapies, cardioversion, and defibrillation when an extravascular implantable cardioverter defibrillator is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias.

The Epsila EV EAZ101 Sternal Tunneling Tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

The Epsila EV EAZ201 Transverse Tunneling Tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

III. CONTRAINDICATIONS

The Aurora EV-ICD MRI SureScan Model DVEA3E4 device is contraindicated for use in the following situations:

- If implanted with a unipolar pacemaker
- If implanted with a device delivering dual-chamber or triple-chamber pacing
- If implanted with a device delivering antitachyarrhythmia therapies
- If incessant ventricular tachyarrhythmia (VT) or ventricular fibrillation (VF) exists
- If the patient's primary disorder is chronic atrial tachyarrhythmia with no concurrent VT or VF
- If symptomatic bradycardia exists
- If tachyarrhythmias with transient or reversible causes exist.

The Epsila EV MRI SureScan Model EV2401 lead is contraindicated for any application that is not specified in the Indications.

The Epsila EV Model EAZ101 Sternal Tunneling Tool is contraindicated for use in patients with a prior sternotomy.
The Epsila EV Model EAZ201 Transverse Tunneling Tools is contraindicated for any application that is not specified in the Indications.

IV. WARNINGS AND PRECAUTIONS

Warnings and precautions for the Aurora EV-ICD System are provided in the product labeling.

V. DEVICE DESCRIPTION

The Aurora EV-ICD System is comprised of the implantable Aurora EV-ICD™ MRI SureScan™ DVEA3E4 extravascular implantable cardioverter defibrillator (EV-ICD), the Aurora EV-ICD Application Software SW041, and the implantable Epsila EV™ MRI SureScan™ EV2401 extravascular lead.

The single use Epsila EV™ EAZ101 Sternal Tunneling Tool and the Epsila EV™ EAZ201 Transverse Tunneling Tool are used as part of the implantation of the System.

Aurora EV-ICD DVEA3E4 Device

The Medtronic Aurora EV-ICD MRI SureScan Model DVEA3E4 single chamber, extravascular implantable cardioverter defibrillator (ICD) is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate. It provides ventricular tachyarrhythmia detection and therapy, post-shock pacing, and prolonged pause detection and therapy (Pause Prevention pacing). The device also provides diagnostic and monitoring features to assist with system evaluation and patient care.

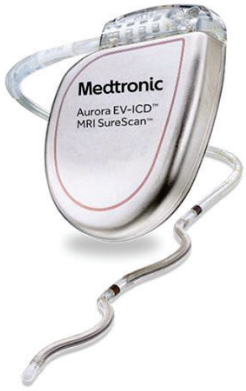

Figure 1. Aurora EV-ICD DVEA3E4

EV-ICD SW041 Application Software

The EV-ICD SW041 application software is intended to provide diagnostic information for the patient which is used by the healthcare professional to make treatment decisions and determine appropriate therapeutic program settings. The EV-ICD SW041 application software package includes all the executable files and data files needed to support programming of the Aurora EV-ICD device on the 2090 and 29901 CareLink Programmer Systems.

Epsila EV2401 Lead

The Medtronic Epsila EV Model EV2401 lead is an extravascular quadripolar lead with shaped passive fixation, designed for sensing, cardioversion, defibrillation, and pacing therapies. The lead has been tested for use in the magnetic resonance imaging (MRI) environment. All lead lengths for this lead model are MR Conditional.

The lead has the ability to pace and sense between the ring and coil electrodes. In addition, the Coil 1 and Coil 2 electrodes deliver cardioversion and defibrillation therapy. The EV4-LLHH1 four-pole inline connector enables connection to an EV4 device during implant. The lead body has a multi-lumen construction, and the lead is free of any pharmacological agents, e.g., steroids.

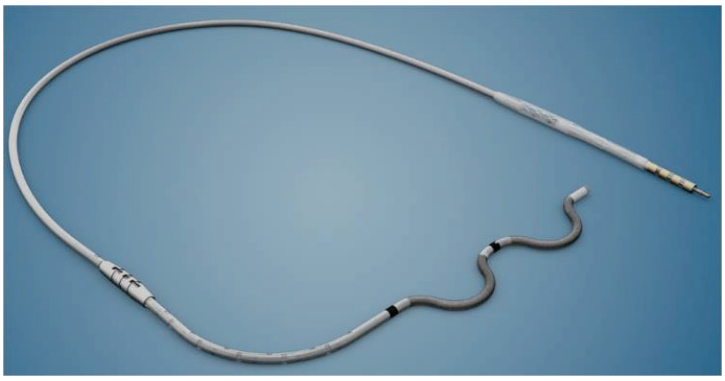

Figure 2. Epsila EV2401 Lead

Epsila EV EAZ101 Sternal Tunneling Tool

The Epsila EV EAZ101 Sternal Tunneling Tool is designed to deliver an introducer and an extravascular lead into the anterior mediastinum during implant of an extravascular implantable device system. The Epsila EV EAZ101 Sternal Tunneling Tool creates a tunnel in the mediastinal space and delivers an introducer to the posterior of the sternum. It has a positive bias intended to allow the tool to maintain contact with the posterior of the sternum. The tunneling rod is malleable to accommodate patient anatomy. The guide rod remains above the skin during tunneling, indicating the path of the tunneling rod and the overall distance the rod has moved within the mediastinal space. The external guide rod is hinged and removable to accommodate user preferences and patient anatomy during tunneling. The thumb tab on the guide rod is used to raise and lower the external guide.

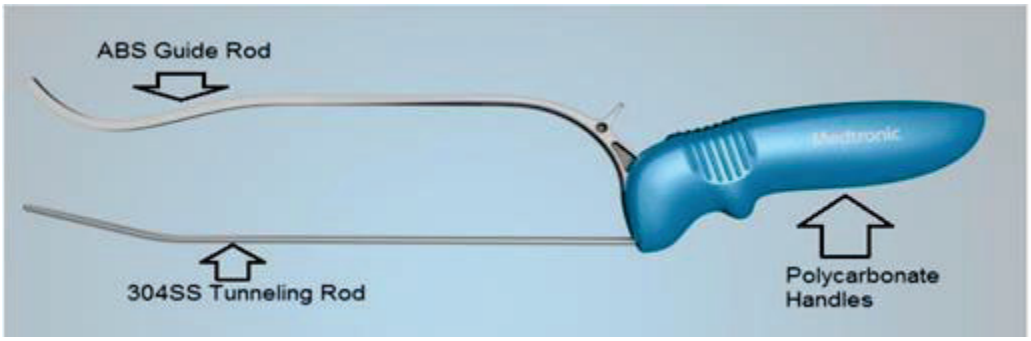

Figure 3: Epsila EV EAZ101 Sternal Tunneling Tool

Epsila EV EAZ201 Transverse Tunneling Tool

The Epsila EV EAZ201 Transverse Tunneling Tool is a tool designed to deliver the proximal portion of an extravascular lead to the device pocket during implant of an extravascular implantable device system. The Epsila EV EAZ201 Transverse Tunneling Tool consists of a handle and a tunneling rod. The tunneling rod has a bullet-shaped tip and the rod can be removed from the handle to expose a channel into which the Epsila EV2401 lead can be secured during tunneling. The flexible polymer tunneling rod and a removable handle are used to gain access from the xiphoid incision to the device pocket. It has a channel that is capable of interfacing with the EV4 connector and allows the lead to be drawn through the tunnel to the device pocket.

Figure 4: Epsila EV EAZ201 Transverse Tunneling Tool

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VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative therapies include the use of antiarrhythmic medication, ablation and cardiac surgery, and other commercially available implantable cardioverter defibrillators. These alternatives have advantages and disadvantages. A patient should fully discuss alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The Aurora EV-ICD System has been distributed commercially outside the United States since September, 2023. Specifically, the Aurora EV-ICD system has been commercially distributed in the following countries: Netherlands, Denmark, Switzerland, Austria, Hungary, Germany, Italy, Spain, New Zealand, and Hong Kong. The device has not been withdrawn from marketing in these markets for any reason related to its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of potential adverse effects associated with the use of the Aurora EV-ICD System:

- Acute tissue trauma
- Allergic reaction
- Bradyarrhythmia
- Cardiac arrest
- Cardiac inflammation
- Cardiac perforation
- Cardiac tamponade
- Death
- Device migration
- Discomfort
- Dizziness
- Dyspnea
- Erosion
- Extracardiac stimulation
- Fever
- Hematoma
- Hemorrhage
- Hemothorax
- Hiccups
- Hospitalization
- Inappropriate shock
- Infection
- Lethargy
- Mental anguish

- Organ damage (liver, mammary arteries, diaphragmatic arteries)
- Palpitations
- Pericardial effusion
- Pericarditis
- Pneumothorax
- Seroma
- Syncope
- Tachyarrhythmia
- Toxic reaction
- Wound dehiscence

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

IX. SUMMARY OF NONCLINICAL STUDIES

A. In Vitro Studies

The EV-ICD System has been evaluated through in-vitro (non-clinical) testing to assure suitability and reliability for its intended use. Design verification testing, and system validation testing demonstrated that the devices meet their design specifications.

1. System Validation

System validation testing is defined as testing against user/stakeholder requirements and intended use scenarios. This testing was performed by evaluating the compatibility, interaction, and functional operation of the system (device, lead, implant tools, programmer, and manuals) using actual and simulated use scenarios covering the functions defined by the project scope. Also included in this testing was product manual validation which validated that the technical statements as written are true and reflect the actual operation of the system. Based on the results of this testing, the Aurora EV-ICD System is considered validated for its intended use.

2. MRI

Validation of the Aurora EV-ICD DVEA3E4 device and the Epsila EV2401 lead for use within an MR environment was completed to support the ability to diagnose patients implanted with the Aurora EV-ICD System using medical imaging.
The MRI environment includes a strong static magnetic field as well as a gradient electromagnetic (time-varying) field and Radiofrequency (RF) electromagnetic (time-varying) field, all of which could potentially interact with the Aurora EV-ICD System. During the development of the Aurora EV-ICD System, potentially hazardous interactions between the Aurora EV-ICD System and the MRI environment were identified and a strategy was developed to evaluate the risks associated with each interaction. When appropriate, design requirements for device performance in the MRI environment were established. The potentially hazardous interactions for the Aurora EV-ICD System are similar to other commercially available MR conditional transvenous systems. The primary differences are related to the new implant location and lead position in the body, which required new use conditions for the MR exposure to be evaluated at those implant conditions. Additionally, some requirements were updated to reflect the different tissues that are in contact with the Epsila EV2401 lead. MRI-induced hazards for the Aurora EV-ICD System were comprehensively evaluated, and the results of those assessments verify

the Aurora EV-ICD System functions as intended during and following exposure to the MRI environment.

3. Cybersecurity

Medtronic has established cybersecurity design inputs for the Aurora EV-ICD System and has also established a cybersecurity vulnerability and management approach as part of the software validation and risk analysis that is required by 21 CFR 820.30(g). This approach addresses the following elements:

- Identification of assets, threats, and vulnerabilities.
- Assessment of the impact of threats and vulnerabilities on device functionality and end users/patients.
- Assessment of the likelihood of a threat and of a vulnerability being exploited.
- Determination of risk levels and suitable mitigation strategies.
- Assessment of residual risk and risk acceptance criteria.

In addition to minimizing cybersecurity and patient safety risks, usability is a key performance indicator for the Aurora EV-ICD System. Thus, efforts have been made to ensure an appropriate risk-based approach to security while maintaining ease of use in the Aurora EV-ICD System.

4. Design Verification Activities

Nonclinical testing for each device was conducted to ensure that the components and the finished devices perform in accordance with their design specifications.

Aurora EV-ICD Device	
Mechanical – Mechanical design verification by review was performed to verify conformance to specification requirements for the Aurora EV-ICD device. The review report concludes that requirements were verified via specification review and/or using computer-aided design software analysis. This provides direct evidence that design specifications met design requirements.	
Component and Sub-Assembly Testing – Specific components and subassemblies of the Aurora EV-ICD were evaluated against their specific requirements. All of the components and subassemblies of the Aurora EV-ICD device were verified for use in their intended applications.	
Feedthrough	The 11-pin feedthrough used on the Aurora EV-ICD device is the same as used on many other market-released ICD devices, and its acceptability for use was documented.
Connector	Most aspects of the connector design are identical between the Aurora EV-ICD and the other Medtronic market-released connectors. The Aurora EV-ICD meets all the requirements for connector mechanical requirements. The Aurora EV-ICD connector is identical to the existing market-released single chamber connector that is already in commercial production, therefore, the connectors are considered equivalent.
High-Voltage Capacitor	The mechanical configuration of Aurora EV-ICD and capacitors are identical to those used in commercially available Medtronic ICDs. Therefore, verification of mechanically related tests such as shock and vibration were done by similarity to other Medtronic MRI capacitor designs. Testing was conducted to qualify the 40J high voltage capacitor for use in the Aurora EV-ICD device.

Battery	The battery used in the Aurora EV-ICD device is the same battery that is used in other market-released ICDs. This was documented via verification review.
Electrical – The electrical design verification activities performed that support the Aurora EV-ICD DVEA3E4 device demonstrate the device meets the electrical requirements. The report concludes that all electrical design requirements were satisfied.	
Environmental	**Electromagnetic Compatibility (EMC) –** EMC verification testing was completed for EV-ICD devices in accordance with ISO 14708-2 and ISO 11117. All EMC device requirements and compliance with standards, where applicable, were met.
	Mechanical Environmental – Mechanical environmental verification activities were performed which supported that the Aurora EV-ICD device meets the mechanical requirements. An analysis report documented that analysis was performed and the Pilot device meets its design requirements.
Firmware – The device firmware documentation provided is consistent with FDA's Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005). The process used for the design and design verification of the EV-ICD firmware is compliant with *IEC 62304:2006 AMDI:2015 (Medical device software – Software life-cycle processes*). Aurora EV-ICD firmware verification testing verified the functionality and performance of the firmware against its firmware requirements, as well as regression testing to demonstrate that all firmware requirements have been correctly implemented.	
Software – The SW041 software includes all the executable and non-executable files and data files needed to support programming the Aurora EV-ICD device on the 2090 and Encore 29901 programmer systems. This software allows the clinician to interrogate and program the device, navigate through the user interface to interact with the implantable device, run tests, set up therapies, perform data analysis, and print reports. Based on the results of the system design validation testing, the Aurora EV-ICD software is validated for its intended use.	
Shelf Life – Packaged and sterilized Aurora EV-ICD devices are labeled with an 18-month shelf life. The purpose of the packaging test was to verify that the packaging protects the device and media during transportation and storage. Verification test results from predicate products and packaging indicate that no further testing is necessary; previous test conclusions remain valid for the Aurora EV-ICD device.	
Packaging – The purpose of the packaging analysis was to verify that the packaging protects the Aurora EV-ICD DVEA3E4 device and media during transportation and storage use conditions. Verification test results from predicate products and packaging indicate that no further testing is necessary; previous test conclusions remain valid for the Aurora EV-ICD device.	
Biocompatibility – Biocompatibility for the EV-ICD device was determined in accordance with EN ISO 10993-1: 2018, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process. The requirements were based on the nature of body contact and contact duration with respect to the device and lead during normal use. Per ISO 10993-1: 2018, the combination of materials, chemicals and processes for the final, finished device was evaluated. Biocompatibility and full compliance with ISO 10993-1:2018 have been demonstrated for the EV-ICD device.	
Sterilization - The Aurora EV-ICD device is sterilized utilizing the 30-minute 100% EO sterilization process. The Aurora EV-ICD device has been successfully qualified into the 30-minute 100% EO sterilization process. A Sterility Assurance Level (SAL) in excess of 10^{-6} is achieved when the Aurora EV-ICD device is sterilized.	
Epsila EV2401 Lead	

Design Verification – The Epsila EV2401 lead has been verified through a combination of test, analysis, and review methods. The reviews conclude that design specifications met design requirements and is considered verified.
Shelf Life – Packaged and sterilized Epsila EV2401 leads are labeled with a 2-year shelf life. Accelerated aging verification was conducted. Following completion of the accelerated aging testing, it was determined that the Epsila EV2401 lead met all requirements.
Packaging – The purpose of the packaging test was to verify that the packaging protects the device and media during transportation and storage use conditions. The test report provides evidence that all requirements for the Epsila EV2401 lead packaging have been met, including both functional and package integrity.
Biocompatibility – A biocompatibility design verification analysis of the Medtronic Model EV2401 lead and its compliance to ISO 10993-1: 2018 was conducted. Analysis determined that the EV2401 lead and the combination of all materials, chemicals, and processes have an acceptable biological risk in their intended use and meets the requirements of ISO 10993-1: 2018.
Sterilization - The Epsila EV2401 lead product family is sterilized utilizing the 30-minute 100% EO sterilization process. The Epsila EV2401 lead product family was successfully sterilized into the 30-minute 100% EO sterilization process. A SAL better than 10^{-6} is achieved when the Epsila EV2401 lead product family is sterilized.
Epsila EV EAZ101 Sternal Tunneling Tool
Design Verification – The Epsila EV EAZ101 Sternal Tunneling Tool has been verified through a combination of test, analysis, and review methods. The outcomes of these verification activities were that the Epsila EV EAZ101 Sternal Tunneling Tool meets its design requirements and is considered verified.
Packaging–The purpose of the packaging test was to verify that the packaging protects the device and media during transportation and storage. The testing concludes that the Epsila EV EAZ101 Sternal Tunneling Tool meets all the requirements and is considered verified.
Sterilization – The Epsila EV EAZ101 Sternal Tunneling Tool is qualified to demonstrate a Sterility Assurance Level (SAL) of $1.0x10^{-6}$ following terminal sterilization via gamma radiation.
Shelf-Life – Shelf-life verification was conducted using verification by analysis leveraging design equivalency to market-released packaging. All materials used in the Epsila EV EAZ101 Sternal Tunneling Tool are the same or similar to other devices which have had acceptable field performance and testing demonstrating a shelf life of 2 years.
Biocompatibility – Biocompatibility for the Epsila EV EAZ101 Sternal Tunneling Tool was determined in accordance with EN ISO 10993-1, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process*. All materials were demonstrated to be biocompatible per ISO 10993-1.
Epsila EV EAZ201 Transverse Tunneling Tool
Design Verification – The Epsila EV EAZ201 Transverse Tunneling Tool has been verified through a combination of test, analysis, and review methods. The outcomes of these verification activities were that the Epsila EV EAZ201 Transverse Tunneling Tool meets its design requirements and is considered verified.
Packaging– Packaged and sterile Epsila EV EAZ201 Transverse Tunneling Tools are labeled with a shelf life of 2 years The testing concludes that the Epsila EV EAZ201 Transverse Tunneling Tool meets all requirements identified in the plan and is considered verified.
Sterilization – The Epsila EV EAZ201 Transverse Tunneling Tool is qualified to demonstrate a Sterility Assurance Level (SAL) of $1.0x10^{-6}$ following terminal sterilization via gamma radiation.

Shelf-Life – Shelf-life verification was conducted using verification by analysis leveraging design equivalency to market-released packaging. All materials used in the Epsila EV EAZ201 Transverse Tunneling Tool are the same or similar to other devices which have had acceptable field performance and testing demonstrating a shelf life of 2 years.
Biocompatibility – Biocompatibility for the Epsila EV EAZ201 Transverse Tunneling Tool was determined in accordance with EN ISO 10993-1, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process*. All materials were demonstrated to be biocompatible per ISO 10993-1.

B. Animal and Additional In Vivo Studies

The safety of substernal pacing, sensing and defibrillation has been demonstrated through pre-clinical animal safety and cadaver evaluations. Further, animal safety studies have demonstrated the safety of substernal tunneling and acute catheter or lead implantation within the substernal tissues.

As observed in Good Laboratory Practice (GLP) animal safety testing, substernal defibrillation is comparable to other forms of defibrillation, including defibrillation from epicardial patch electrodes and leads placed within the pericardial sac. According to comparisons with historical animal studies and published literature, substernal defibrillation is also comparable to transvenous defibrillation, the accepted standard of care for treating arrhythmias with an implantable device.

Across all GLP animal safety studies, no cardiac lesion, test or control, measured greater than two cubic centimeters (cc). MRI characterization of cardiac lesions in human patients has demonstrated that lesions of less than two cubic centimeters are regarded as subclinical in nature and not indicative of long-term sequelae.

Across all animal safety studies, no damage was observed to the lungs, kidneys, spleen or liver, and any observed changes to the substernal tissues were minor and expected to heal in time.

Table 1. Additional In Vivo Testing

Study Name / Identifier	Study Purpose	Results
EV ICD Lead Shape and Tip Displacement Measurements in Canines	Assess lead bend in vivo to inform reliability testing	All electrode regions experience similar conditions for a given implant. Implant locations closest to the heart cause highest displacement and curvature. These measurements, along with fatigue test data, were used to estimate long-term reliability to verify the lead design meets requirements

Study Name / Identifier	Study Purpose	Results
Thompson AE, Marshall M, Lentz L, Mazzetti H. Three-year extraction experience of a novel substernal extravascular defibrillation lead in sheep. Pacing Clin Electrophysiol. 2022; 45: 314–322. https://doi.org/10.1111/pace.14451	5-year lead extraction study. (Three-year extraction data are available as a published manuscript)	Chronic extraction of EV ICD leads from the substernal space was successfully performed using traction and simple tools through 3 years in sheep
EV ICD Chronic Lead Study (S3922)	Characterize chronic tissue encapsulation	Histopathological comparisons of chronically implanted EV ICD and transvenous ICD control leads in 5 swine revealed tissue capsules of similar thickness, maturity, and inflammatory response at 12 weeks
EV ICD Lead Axial Force Measurement due to Posturing in Human Cadavers Extravascular ICD Lead Use Conditions due to Postures Simulated in Human Cadavers	Use of cadavers for lead stability testing and lead fatigue inputs	All encountered tissue changes (pockets, subcutaneous lead portions, distal lead portions) were found to be within an expected range of responses for procedures of similar type and duration

X. SUMMARY OF PRIMARY CLINICAL STUDY

EV-ICD Pivotal Study

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of substernal implant with the EV-ICD System for substernal pacing in the United States (US)/Canada, Asia Pacific (APAC), and Europe, Middle, East and Africa (EMEA) regions under IDE #G190186. The EV-ICD Pivotal study is a prospective, multi-center, single-arm, pre-market clinical study, designed to demonstrate the safety and efficacy of the EV-ICD System. The study enrolled 356 subjects. A total of 299 subjects were successfully implanted with the full system by 55 physicians at 46 centers across 17 countries. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

This study was a prospective, multi-center, single-arm, pre-market clinical study. The purpose of this clinical study was to demonstrate the safety and efficacy of the EV-ICD System. The study design allowed for up to 400 enrollments at up to 60 sites worldwide, to allow at least 292 subjects to, in the case of the safety objective, undergo an implant attempt of the EV-ICD System, and in the case of the efficacy objective, complete the pre-specified defibrillation testing protocol.

The first worldwide subject was enrolled in the EV-ICD Pivotal Clinical Study on 16 September 2019 and underwent an EV-ICD implant the same day. On 15 October 2021, the last subject underwent an implant attempt, completing the enrollment and implant phase of the study. On 28 April 2022, the final 6-month follow-up visit was completed, triggering the visit cutoff date for the PMA report analysis. Case report form data analyzed for this PMA report was collected on or before 28 April 2022 and was received at Medtronic on or before 13 May 2022. The study database was frozen for analysis on 7 June 2022.

As of the 28 April 2022 visit cutoff date, 356 subjects were enrolled in the study, of which 316 underwent an implant attempt with the EV-ICD System. Of the 316 subjects who underwent an implant attempt, the substernal lead was positioned in 315. A total of 299 subjects were successfully implanted with the full system by 55 physicians at 46 centers across 17 countries.

Maximum number of subjects enrolled at each site was capped at 35, which is approximately 10% of the total number of subjects enrolled.

Subjects indicated for single-chamber ICD therapy were recruited and implanted with the Medtronic EV-ICD System. Once enrolled, subjects were assessed at the following visits:

- Baseline
- Implant
- Pre-Hospital Discharge (PHD)
- 2 Weeks (2WK)
- 3 Months (3M)
- 6 Months (6M)
- Long-term: Every 6 months thereafter until study closure (12, 18, 24… Months)
- Unscheduled (as they occur)
- System Modifications (as they occur)
- Exit

The primary safety objective was to demonstrate the freedom from major complications related to the EV-ICD System and/or procedure at 6 months post-implant exceeds 79% performance goal (PG). The endpoint was defined as a subject's first occurrence of a major complication related to the EV-ICD System and/or procedure, as determined by an independent Clinical Events Committee (CEC), that occurs on or prior to 6 months (182 days) post-implant.

To evaluate the safety primary objective, a 95% confidence interval for the Kaplan-Meier estimate of 6-month system/procedure related major complication-free rate was generated using the log-log transformation and its lower bound compared against the pre-specified threshold of 79%. A Kaplan-Meier curve was also generated to provide incidence of EV-ICD System/procedure-related major complications over time.

The primary efficacy objective was to demonstrate the defibrillation efficacy at implant of the EV-ICD System exceeds 88% (PG). The endpoint, defibrillation testing success, was defined as:

- Single sustained shockable ventricular arrhythmia (SSVA) conversion at 20J, or
- Conversion of two consecutive episodes of SSVA at 30J in final system configuration.

The efficacy primary objective was evaluated using an exact binomial 95% confidence interval and comparing the lower bound against the pre-specified threshold of 88%.

The sponsor consulted with the Steering Committee before and during the course of the study.

1. Clinical Events Committee

A Clinical Events Committee (CEC) consisted of physicians independent of the study was used to review and adjudicate adverse events (AEs) for their relationship to the EV-ICD Pivotal system and/or procedure.

2. Data Monitoring Committee

A Data Monitoring Committee (DMC) consisted of members independent of the study is used to periodically review the total incidence of AEs and follow trends of these events in the study, and to make recommendations to Medtronic and/or the Steering Committee regarding study conduct and subject safety. An Episode Review Committee (ERC) consisted of independent physicians and Medtronic experts was used to evaluate device-treated ventricular episodes according to an ERC Charter.

3. Clinical Inclusion and Exclusion Criteria

Enrollment in the EV-ICD Pivotal study was limited to patients who met the following inclusion criteria:

	Inclusion Criteria
1.	Patient has a Class I or IIa indication for implantation of an ICD according to the ACC/AHA/HRS Guidelines[a], or ESC guidelines[b].
2.	Patient is at least 18 years of age and meets age requirements per local law.
3.	Patient is geographically stable and willing and able to complete the study procedures and visits for the duration of the follow-up.

Patients were not permitted to enroll in the EV-ICD Pivotal study if they met any of the following exclusion criteria:

	Exclusion Criteria
1.	Patient is unwilling or unable to personally provide Informed Consent.
2.	Patient has indications for bradycardia pacing[c] or Cardiac Resynchronization Therapy (CRT)[d] (Class I, IIa, or IIb indication).

a Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias.

b Priori SG, Blomstrom-Lundqvist C, Mazzanti A, et al. 2015 ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. European Heart Journal 2015 36:41 (2793-2867). https://doi.org/10.1093/eurheartj/ehv316

c 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing).

d ACC/AHA/HRS guidelines for Cardiac Resynchronization Therapy

	Exclusion Criteria
3.	Patients with an existing pacemaker, ICD, or CRT device or leads.
4.	Patients with these medical interventions are excluded from participation in the study: 1. Prior sternotomy 2. Any prior medical condition or procedure that leads to adhesions in the anterior mediastinal space (i.e., prior mediastinal instrumentation, mediastinitis) 3. Prior abdominal surgery in the epigastric region 4. Planned sternotomy 5. Prior chest radiotherapy Or any other prior/planned medical intervention not listed that precludes their participation in the opinion of the Investigator.
5.	Patient has previous pericarditis that: • Was chronic and recurrent, or • Resulted in pericardial effusion[e], or Resulted in pericardial thickening or calcification.[f]
6.	Patients with these medical conditions or anatomies are excluded from participation in the study: – Hiatal hernia that distorts mediastinal anatomy – Marked sternal abnormality (e.g., pectus excavatum) – Decompensated heart failure – COPD with oxygen dependence – Gross hepatosplenomegaly Or any other known medical condition or anatomy type not listed that precludes their participation in the opinion of the Investigator.

e As documented on echo or MRI
f As documented on CT scan or MRI

	Exclusion Criteria
7.	Patients with a medical condition that precludes them from undergoing defibrillation testing: — Severe aortic stenosis — Current Intracardiac Left Atrium (LA) or Left Ventricular (LV) thrombus — Severe proximal three-vessel or left main coronary artery disease without revascularization — Hemodynamic instability — Unstable angina — Recent stroke or transient ischemic attack (within the last 6 months) — Known inadequate external defibrillation — Left Ventricular Ejection Fraction (LVEF) < 20% — Left Ventricular End Diastolic Diameter (LVEDD) >70 mm Or any other known medical condition not listed that precludes their participation in the opinion of the Investigator.
8.	Patient with any evidence of active infection or undergoing treatment for an infection.
9.	Patient is contraindicated from temporary suspension of oral/systemic anticoagulation
10.	Patient with current implantation of neurostimulator or any other chronically implanted device that delivers current in the body.
11.	Patient meets ACC/AHA/HRS or ESC clinical guideline Class III criteria for an ICD (e.g., life expectancy of less than 12 months).
12.	Patient is enrolled or planning to enroll in a concurrent clinical study that may confound the results of this study, without documented pre-approval from a Medtronic study
13.	Patient with any exclusion criteria as required by local law (e.g., age or other).
14.	Pregnant women or breastfeeding women, or women of child bearing potential and who are not on a reliable form of birth regulation method or abstinence.[g]

4. Follow-up Schedule

This is a single-arm study. After subjects signed the informed consent form, they were enrolled in the study. Extensive inclusion/exclusion criteria have been chosen in this study to restrict the target population to those thought to be best served by this EV-ICD system and mitigate the risk of selection bias as well as to exclude subjects who may be more vulnerable to potential increased risk during the evaluation of the clinical study defibrillation protocol. Enrollment could be a stand-alone visit or could occur on the same day as the baseline visit. After that, subjects underwent implant of the EV-ICD system, with required defibrillation, sensing, impedance and pacing

g If required by local law, women of child-bearing potential must undergo a pregnancy test within seven days prior to EV-ICD Pivotal Study procedures

testing. Subjects then returned for follow-up visits at 2 Weeks, 3 Months, 6 Months, and every 6 months thereafter. Refer to **Table 2** for the schedule of events for the Pivotal study visit.

Table 2. EV-ICD Pivotal Study schedule of events

Study procedure	Baseline	Implant	PHD	2 Weeks	3 Months	6 Months	Long-Term (12, 18, 24… months)	Unsched.	Sys. Mod.	Exit
Informed Consent	X									
Inclusion/Exclusion Assessment	X									
Physical Exam, Demographics, Cardiovascular Medical History, Surgical History	X									
SF-12 quality of life survey	X					X				
Florida Patient Acceptance Survey (FPAS)[1]						X				
System and procedure information		X							X	
Pre-procedure Transesophageal Echocardiogram (TEE)[2]		X[2]								
CT or MRI scan	X[3]									
Fluoroscopy recordings during tunneling procedure		X							X[6]	
Fluoroscopy (AP and Lateral cine) of final ICD generator and lead position		X							X[6]	
Sensing, Impedance & Pacing Tests		X	X	X	X	X	X	X[5]	X[6]	
Defibrillation Testing		X				Subset[4]			X[6]	
Chest Radiographs – (PA/Lateral)	X		X			X				
Echocardiographic data within the last 6 months	X									
Save-to-media files		X	X	X	X	X	X	X	X	X
Medications (for subjects implanted with any device)	X	X	X	X	X	X	X	X	X	X
Adverse Events[7] (including AEs with fatal outcome), Device Deficiencies, HCUs, Study Deviations, and Other Cardiac Imaging	As they occur									

[1] Only for subjects who complete their Informed Consent Form (ICF) in English.
[2] Required for subjects presenting in persistent atrial fibrillation to confirm the absence of Left Atrium (LA) or Left Ventricular (LV) thrombus.
[3] Taken within the last year. Recommended for first 3 subjects at minimum, for each implanter. If collected/reviewed, send CT-scan and/or MRI to Medtronic.
[4] Only for subjects participating in chronic defibrillation testing, see CIP Addendum for 6-Month Defibrillation Testing.
[5] Optional. If electrical testing conducted, print the Testing Reports to PDF or paper and send a copy of the reports to Medtronic
[6] System modification where a subject leaves the procedure with an EV-ICD System.
[7] Recommended to collect incision photographs if an infection related to the EV ICDEV-ICD System is suspected.

5. Clinical Endpoints

With regards to safety, the primary safety objective was to demonstrate the freedom from major complications related to the EV-ICD System and/or procedure at 6 months post-implant exceeds 79% performance goal (PG). The endpoint was defined as a subject's first occurrence of a major complication related to the EV-ICD System and/or procedure, as determined by an independent Clinical Events Committee (CEC), that occurred on or prior to 6 months (182 days) post-implant.

For an adverse event to meet the endpoint, the event must have occurred within 182 days (inclusive) of the EV-ICD System implant and been adjudicated by the CEC as being a major complication related (causal relationship) to the EV-ICD System and/or procedure. Major complications were those complications resulting in:

- Death
- Permanent loss of defibrillation function (specifically shock) due to mechanical or electrical dysfunction of the device
- Hospitalization
- Prolongation of an existing hospitalization by at least 48 hours
- System revision (reposition, replacement, explant)

With regards to effectiveness, the primary efficacy objective was to demonstrate the defibrillation efficacy at implant of the EV-ICD System exceeds 88% (PG). The endpoint, defibrillation testing success, was defined as:

- Single sustained shockable ventricular arrhythmia (SSVA) conversion at 20J, or
- Conversion of two consecutive episodes of SSVA at 30J in final system configuration.

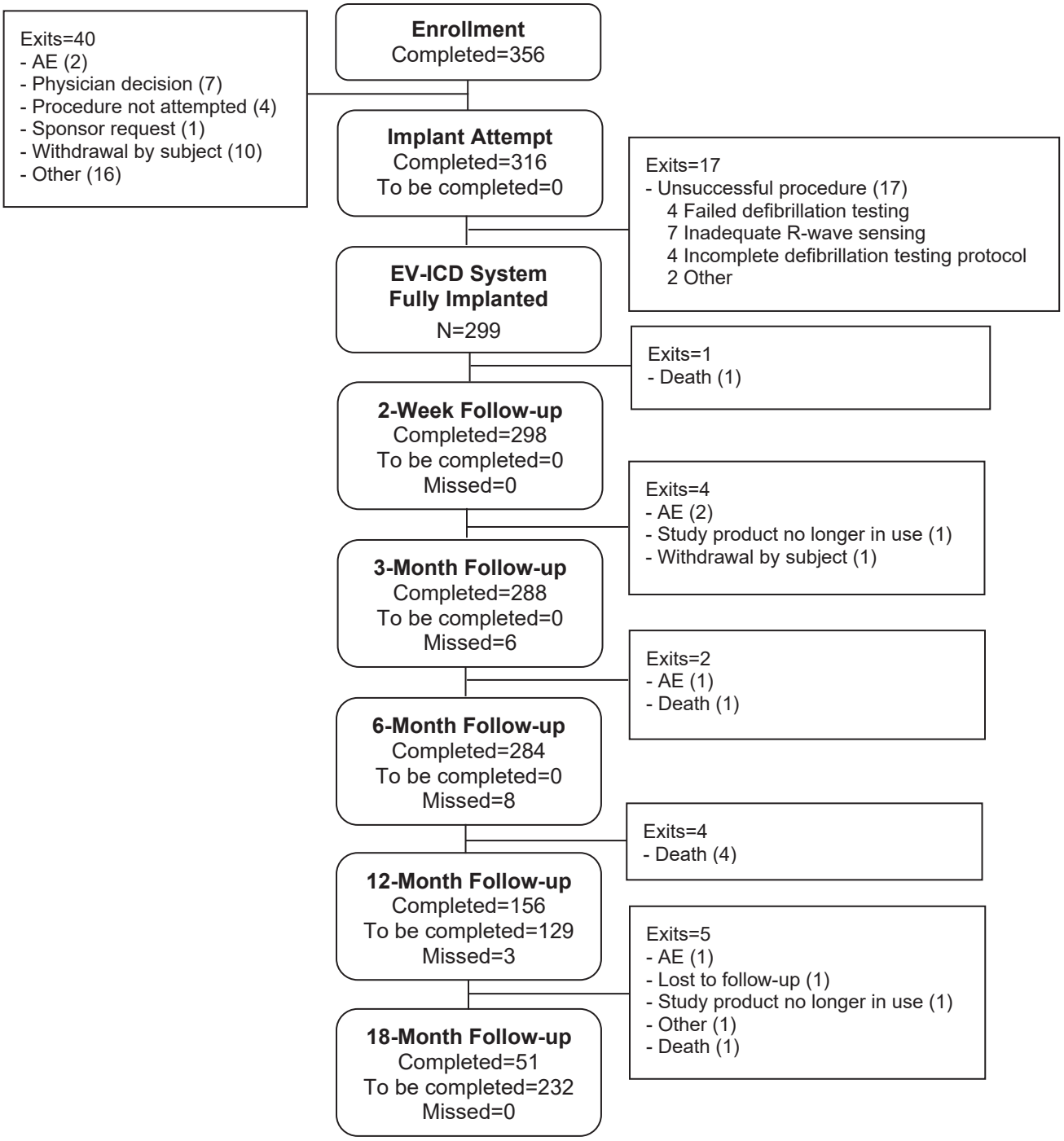
C. Accountability of PMA Cohort

Among 356 enrolled subjects, 40 exited the study without having an implant attempt and 316 underwent an implant attempt of the EV-ICD System. Of the 316 subjects who underwent an implant attempt, 315 subjects had the lead positioned and proceeded to electrical testing during the implant procedure. In total, 299 (94.6%) had the EV-ICD System fully implanted and 17 did not. Reasons for not having a successful implant included:

- Failed defibrillation testing (4)
- Inadequate R-wave sensing (7)
- Incomplete defibrillation testing protocol (4)
- Other reasons (2)
    - Tunneling stopped due to resistance
    - Oversensing of atrial fibrillation in all lead positions attempted

All 17 subjects with an unsuccessful implant exited the study following the instructions in the Clinical Investigational Protocol (CIP). Of them, 15 subjects exited between 28-36 days post implant attempt and two subjects exited 54 and 70 days post implant attempt, respectively.

Subject disposition is presented using a flow diagram (refer to **Figure 5**) where completed visits, missed visits, and attrition due to exit and death are indicated.



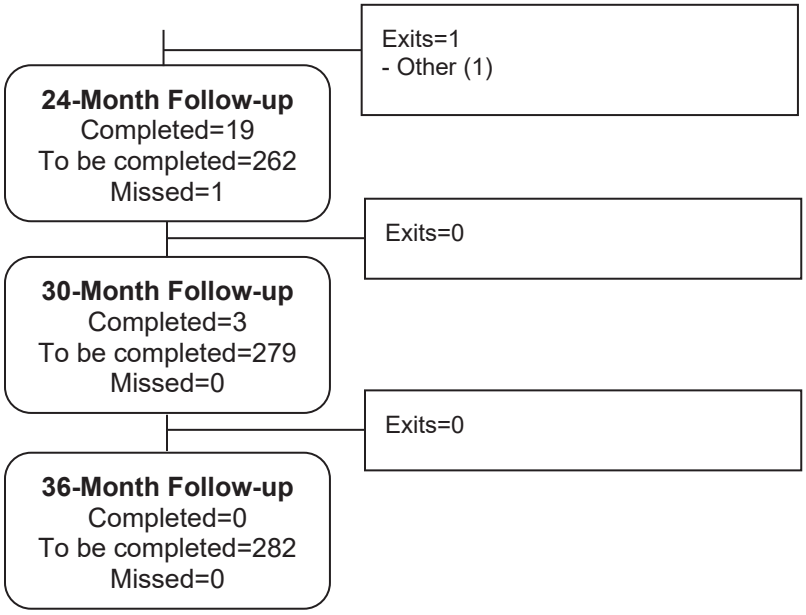


Figure 5: Subject Disposition Diagram

D. Study Population Demographics and Baseline Parameters

The demographics of the study population are younger than typical ICD recipients, with a high frequency of hypertrophic cardiomyopathy.

Baseline characteristics are summarized in **Table 3** – **Table 13**.

Among 356 subjects enrolled, 343 had baseline forms completed at the time of this report, and all subjects without a baseline form have been exited. There were 316 subjects with an implant attempt; of these, 74.7% were male, the average age (±standard deviation) was 53.8 ± 13.1 years, the average BMI (±standard deviation) was 28.0 ± 5.6, 23.7% were known to be NYHA Class I and 65.5% were known to be NYHA Class II/III.

Of those with an implant attempt, 258 (81.6%) were indicated for primary prevention as defined in **Table 6**, 57 (18.0%) were indicated for secondary prevention and 1 (0.3%) did not provide enough information to classify as primary or secondary.

Of the 18 subjects with an explanted device indicated in cardiovascular surgical history (**Table 11**), ten had their explant within two weeks prior to enrollment, seven had their explant more than two weeks prior to enrollment with a maximum of 258 days, and one had their explant 33 days after enrollment but seven days prior to EV-ICD implant.

Table 3: Subject Demographics

	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Sex (N,%)			
Male	236 (74.7%)	22 (81.5%)	258 (75.2%)
Female	80 (25.3%)	5 (18.5%)	85 (24.8%)
Age (years)			
Mean ± Standard Deviation	53.8 ± 13.1	53.3 ± 14.7	53.8 ± 13.2
Median	55.0	55.0	55.0
25^{th} Percentile - 75^{th} Percentile	46 - 64	43 - 68	46 - 64
Minimum - Maximum	18 - 84	19 - 76	18 - 84
Number Of Subjects With Measure Available (N, %)	316 (100.0%)	27 (100.0%)	343 (100.0%)
Number of Subjects 90 Years or Older	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ethnicity (N,%)			
Not Reported due to local requirements (Non-US)	197 (62.3%)	10 (37.0%)	207 (60.3%)
Not Reported for other reasons	2 (0.6%)	0 (0.0%)	2 (0.6%)
Not Hispanic or Latino	110 (34.8%)	17 (63.0%)	127 (37.0%)
Hispanic or Latino	7 (2.2%)	0 (0.0%)	7 (2.0%)
Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
Race (N,%)			
Not Reported due to local requirements (Non-US)	197 (62.3%)	10 (37.0%)	207 (60.3%)
Not Reported for other reasons	0 (0.0%)	0 (0.0%)	0 (0.0%)
American Indian or Alaska Native	2 (0.6%)	0 (0.0%)	2 (0.6%)
Asian	7 (2.2%)	1 (3.7%)	8 (2.3%)
Black or African American	16 (5.1%)	1 (3.7%)	17 (5.0%)
Native Hawaiian or Other Pacific Islander	1 (0.3%)	0 (0.0%)	1 (0.3%)

	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
White	87 (27.5%)	15 (55.6%)	102 (29.7%)
Other	6 (1.9%)	0 (0.0%)	6 (1.7%)

Table 4: Physical Exam Results

Status	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Height (cm)			
Mean ± Standard Deviation	173.8 ± 9.4	172.9 ± 10.0	173.8 ± 9.4
Median	174.0	172.7	174.0
25th Percentile – 75th Percentile	167 - 180	165 - 182	167 - 180
Minimum – Maximum	145 - 203	147 - 188	145 - 203
Number of Subjects With Measure Available (N,%)	316 (100.0%)	27 (100.0%)	343 (100.0%)
Weight (kg)			
Mean ± Standard Deviation	85.1 ± 19.7	83.8 ± 20.7	85.0 ± 19.8
Median	83.0	85.3	83.0
25th Percentile – 75th Percentile	70 - 96	69 - 93	70 - 96
Minimum – Maximum	48 - 148	49 - 137	48 - 148
Number of Subjects With Measure Available (N,%)	316 (100.0%)	27 (100.0%)	343 (100.0%)
BMI (kg/m^2)			
Mean ± Standard Deviation	28.0 ± 5.6	27.9 ± 5.7	28.0 ± 5.6
Median	27.7	27.5	27.7
25th Percentile – 75th Percentile	24 - 31	24 - 33	24 - 32
Minimum – Maximum	18 - 46	17 - 41	17 - 46
Number of Subjects With Measure Available (N,%)	316 (100.0%)	27 (100.0%)	343 (100.0%)

Table 5: Cardiac Disease Classification Characteristics

Status	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
New York Heart Association (N,%)			
Class I	75 (23.7%)	5 (18.5%)	80 (23.3%)
Class II	184 (58.2%)	17 (63.0%)	201 (58.6%)
Class III	23 (7.3%)	4 (14.8%)	27 (7.9%)
Class IV	0 (0.0%)	0 (0.0%)	0 (0.0%)
NYHA classification not available	34 (10.8%)	1 (3.7%)	35 (10.2%)

Table 6: Summary of ICD Indication

	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Primary prevention	**258 (81.6%)**	**25 (92.6%)**	**283 (82.5%)**
LVEF<=35% due to prior MI, NYHA Class II or III	94 (29.7%)	9 (33.3%)	103 (30.0%)
Nonischemic dilated cardiomyopathy, LVEF <=35%, NYHA Class II/III	76 (24.1%)	8 (29.6%)	84 (24.5%)
LV dysfunction due to prior MI, LVEF <=30%, NYHA Class I	14 (4.4%)	2 (7.4%)	16 (4.7%)
NSVT due to prior MI, LVEF<40%, inducible VT/VF	1 (0.3%)	1 (3.7%)	2 (0.6%)
Hypertrophic cardiomyopathy, 1 or more major risk factors for SCD	33 (10.4%)	2 (7.4%)	35 (10.2%)
Arrhythmogenic RV dysplasia/cardiomyopathy, 1 or more risk factor for SCD	5 (1.6%)	0 (0.0%)	5 (1.5%)
Brugada syndrome and has had syncope	1 (0.3%)	0 (0.0%)	1 (0.3%)

	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Brugada syndrome and has documented VT that has not resulted in cardiac arrest	1 (0.3%)	0 (0.0%)	1 (0.3%)
Cardiac sarcoidosis, giant cell myocarditis, or Chagas disease	3 (0.9%)	0 (0.0%)	3 (0.9%)
Nonischemic heart disease, LVEF <=35%, NYHA functional Class I	9 (2.8%)	0 (0.0%)	9 (2.6%)
Long-QT Syndrome and risk factors for SCD	1 (0.3%)	0 (0.0%)	1 (0.3%)
Familial cardiomyopathy associated with sudden death	13 (4.1%)	1 (3.7%)	14 (4.1%)
LV noncompaction	0 (0.0%)	2 (7.4%)	2 (0.6%)
Other primary prevention*	7 (2.2%)	0 (0.0%)	7 (2.0%)
Secondary prevention	**57 (18.0%)**	**2 (7.4%)**	**59 (17.2%)**
Cardiac arrest due to VF/hemodynamically unstable sustained VT	40 (12.7%)	1 (3.7%)	41 (12.0%)
Structural heart disease and spontaneous sustained VT	6 (1.9%)	1 (3.7%)	7 (2.0%)
Syncope with induced sustained VT/VF	1 (0.3%)	0 (0.0%)	1 (0.3%)
Unstable VT and/or VT with syncope and LVEF<=40%	4 (1.3%)	0 (0.0%)	4 (1.2%)
Sustained VT and normal ventricular function	6 (1.9%)	0 (0.0%)	6 (1.7%)
Other**	**1 (0.3%)**	**0 (0.0%)**	**1 (0.3%)**

** Other primary prevention indications for subjects with an Implant Attempt included "FAMILIAL IDIOPATHIC VF (DPP6 GENE)" (2), "ISCHAEMIC CARDIOMYOPATHY, LVEF 30%, NYHA II" (1), "ISCHEMIC CARDIOMYOPATHY AND HAS AN LVEF LESS THAN OR EQUAL TO 35% AND IS IN NYHA FUNCTIONAL CLASS II OR III" (1), "ISCHEMIC CARDIOMYOPATHY, HAS AN LVEF LESS THAN OR EQUAL TO 30% AND IS IN NYHA FUNCTIONAL CLASS I(WITHOUT MYOCARDIAL INFRACTION DOCUMENTED" (1), "ISCHEMIC CARDIOPATHY, ELF 35%, NYHA II" (1), and "ISCHEMIC HEART DISEASE, LVEF LESS THAN 35%, NYHA II"(1).*

*** Other unclassified indication included "STRUCTURAL HEART DISEASE WITH NON-SUSTAINED VT" (1).*

Table 7: EP Testing and ECG Characteristics

Status	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
EP Testing Within Last 180 Days (N,%)			
Not done	308 (97.5%)	26 (96.3%)	334 (97.4%)
Non-inducible ventricular arrhythmias	2 (0.6%)	0 (0.0%)	2 (0.6%)
Inducible, specify	**6 (1.9%)**	**1 (3.7%)**	**7 (2.0%)**
Sustained VF	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-sustained VF	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular flutter	1 (0.3%)	0 (0.0%)	1 (0.3%)
Ventricular fibrillation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sustained monomorphic VT	2 (0.6%)	1 (3.7%)	3 (0.9%)
Sustained polymorphic VT	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sustained VT, morphology unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-sustained VT (5 beats or less)	1 (0.3%)	0 (0.0%)	1 (0.3%)
Torsades de Pointes	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other*	2 (0.6%)	0 (0.0%)	2 (0.6%)

** Other indications included "NON DIAGNOSTIC STUDY – NO ARRHYTHMIAS INDUCED" (1) and "NON INDUCIBLE SVT ON MONITOR > 3 MIN" (1).*

Table 8: Imaging Testing Results

Status	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Methods Used for LVEF Measurement (%)			
Transthoracic Echocardiography	303 (95.9%)	27 (100.0%)	330 (96.2%)
Stress Echocardiography	1 (0.3%)	0 (0.0%)	1 (0.3%)
Transesophageal Echocardiography	11 (3.5%)	0 (0.0%)	11 (3.2%)
Other	1 (0.3%)	0 (0.0%)	1 (0.3%)
Echo Not Done	0 (0.0%)	0 (0.0%)	0 (0.0%)
LV Ejection Fraction (%)			
Mean ± Standard Deviation	38.9 ± 15.4	36.0 ± 12.5	38.7 ± 15.2
Median	33.0	35.0	33.0

Status	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
25th Percentile – 75th Percentile	27 - 53	28 - 45	27 - 51
Minimum – Maximum	20 - 85	15 - 70	15 - 85
Number of Subjects With Measure Available	316 (100.0%)	27 (100.0%)	343 (100.0%)
LV End Diastolic Volume (mL)			
Mean ± Standard Deviation	158.7 ± 69.9	146.4 ± 57.0	157.7 ± 69.0
Median	150.0	136.2	150.0
25th Percentile – 75th Percentile	110 - 197	116 - 194	110 - 196
Minimum – Maximum	5 - 503	38 - 255	5 - 503
Number of Subjects With Measure Available	244 (77.2%)	20 (74.1%)	264 (77.0%)
LV End Diastolic Diameter (mm)			
Mean ± Standard Deviation	55.8 ± 9.2	56.1 ± 10.3	55.8 ± 9.2
Median	57.0	58.0	57.0
25th Percentile – 75th Percentile	50 - 62	50 - 61	50 - 62
Minimum – Maximum*	22 - 72	31 - 75	22 - 75
Number of Subjects With Measure Available	314 (99.4%)	27 (100.0%)	341 (99.4%)
LA Systolic Diameter (mm)			
Mean ± Standard Deviation	40.4 ± 11.8	44.2 ± 10.9	40.7 ± 11.8
Median	41.0	44.0	41.0
25th Percentile – 75th Percentile	35 - 46	38 - 50	35 - 46
Minimum – Maximum	3 - 93	21 - 72	3 - 93
Number of Subjects With Measure Available	260 (82.3%)	23 (85.2%)	283 (82.5%)
RA Size (N,%)			
Normal	223 (70.6%)	14 (51.9%)	237 (69.1%)
Enlarged	69 (21.8%)	9 (33.3%)	78 (22.7%)
Measure not available	24 (7.6%)	3 (11.1%)	27 (7.9%)

* *LVEDD > 70 is an exclusion criterion for this study. Two deviations have been completed for the two patients with an implant attempt and an LVEDD of 71 and 72.*

Table 9: Spontaneous Arrhythmia History

Status*	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None	**127 (40.2%)**	**7 (25.9%)**	**134 (39.1%)**
Supraventricular tachycardia			
Atrial fibrillation	**44 (13.9%)**	**8 (29.6%)**	**52 (15.2%)**
Paroxysmal	28 (8.9%)	2 (7.4%)	30 (8.7%)
Persistent	8 (2.5%)	6 (22.2%)	14 (4.1%)
Long-standing persistent	4 (1.3%)	1 (3.7%)	5 (1.5%)
Permanent	5 (1.6%)	1 (3.7%)	6 (1.7%)
Atrial flutter	7 (2.2%)	4 (14.8%)	11 (3.2%)
Atrial tachycardia	7 (2.2%)	1 (3.7%)	8 (2.3%)
Sinus node dysfunction (any of the following)	**34 (10.8%)**	**5 (18.5%)**	**39 (11.4%)**
Bradycardia-tachycardia syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronotropic incompetence	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus arrest/pause/exit block	1 (0.3%)	0 (0.0%)	1 (0.3%)
Sinus bradycardia	19 (6.0%)	3 (11.1%)	22 (6.4%)
Sinus tachycardia	16 (5.1%)	2 (7.4%)	18 (5.2%)
Ventricular arrhythmias	**135 (42.7%)**	**9 (33.3%)**	**144 (42.0%)**
Premature ventricular complexes	41 (13.0%)	1 (3.7%)	42 (12.2%)
Torsades de pointes	2 (0.6%)	0 (0.0%)	2 (0.6%)
Ventricular fibrillation	32 (10.1%)	1 (3.7%)	33 (9.6%)
Ventricular flutter	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular tachycardia non-sustained	70 (22.2%)	7 (25.9%)	77 (22.4%)
Ventricular tachycardia, sustained monomorphic	14 (4.4%)	0 (0.0%)	14 (4.1%)
Ventricular tachycardia, sustained polymorphic	4 (1.3%)	1 (3.7%)	5 (1.5%)
Ventricular tachycardia, sustained unknown	10 (3.2%)	0 (0.0%)	10 (2.9%)
AV block	**12 (3.8%)**	**2 (7.4%)**	**14 (4.1%)**
1st degree AV block	12 (3.8%)	2 (7.4%)	14 (4.1%)
2nd degree AV block	3 (0.9%)	0 (0.0%)	3 (0.9%)
3rd degree AV block	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bundle branch blocks	**22 (7.0%)**	**2 (7.4%)**	**24 (7.0%)**
Left bundle branch block	5 (1.6%)	0 (0.0%)	5 (1.5%)
Intraventricular conduction delay	9 (2.8%)	1 (3.7%)	10 (2.9%)
Right bundle branch block	11 (3.5%)	1 (3.7%)	12 (3.5%)

** Categories in medical history tables may not be mutually exclusive.*

Table 10: Cardiovascular History

Status*	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None of the following	**4 (1.3%)**	**0 (0.0%)**	**4 (1.2%)**
Cardiac arrest	45 (14.2%)	2 (7.4%)	47 (13.7%)
Cardiomyopathy	**265 (83.9%)**	**25 (92.6%)**	**290 (84.5%)**
Ischemic	128 (40.5%)	12 (44.4%)	140 (40.8%)
Non-ischemic	102 (32.3%)	12 (44.4%)	114 (33.2%)
Hypertrophic	41 (13.0%)	2 (7.4%)	43 (12.5%)
Coronary artery disease	147 (46.5%)	16 (59.3%)	163 (47.5%)
Hypertension	155 (49.1%)	12 (44.4%)	167 (48.7%)
Hypotension	8 (2.5%)	0 (0.0%)	8 (2.3%)
Idiopathic structural heart disease	9 (2.8%)	2 (7.4%)	11 (3.2%)
Left ventricular hypertrophy	52 (16.5%)	4 (14.8%)	56 (16.3%)
Myocardial infarction	132 (41.8%)	13 (48.1%)	145 (42.3%)
Primary/idiopathic electrical disease (of the following)	**24 (7.6%)**	**2 (7.4%)**	**26 (7.6%)**
Arrhythmogenic RV dysplasia	6 (1.9%)	0 (0.0%)	6 (1.7%)
Brugada syndrome	2 (0.6%)	0 (0.0%)	2 (0.6%)
Long Q/T syndrome	5 (1.6%)	0 (0.0%)	5 (1.5%)
Unknown type	2 (0.6%)	1 (3.7%)	3 (0.9%)
Other	9 (2.8%)	1 (3.7%)	10 (2.9%)
Stroke and stroke-related events	**24 (7.6%)**	**3 (11.1%)**	**27 (7.9%)**
Stroke, ischemic	14 (4.4%)	1 (3.7%)	15 (4.4%)
Stroke, hemorrhagic	1 (0.3%)	0 (0.0%)	1 (0.3%)
Thromboembolism	6 (1.9%)	1 (3.7%)	7 (2.0%)
Transient ischemic attack	8 (2.5%)	1 (3.7%)	9 (2.6%)
Syncope	**32 (10.1%)**	**4 (14.8%)**	**36 (10.5%)**
Due to arrhythmia	13 (4.1%)	3 (11.1%)	16 (4.7%)
Due to no arrhythmia causes	3 (0.9%)	1 (3.7%)	4 (1.2%)
Unexplained/unknown	17 (5.4%)	0 (0.0%)	17 (5.0%)
Vascular disease	28 (8.9%)	2 (7.4%)	30 (8.7%)

** Categories in medical history tables may not be mutually exclusive.*

Table 11: Cardiovascular Surgical History

Status*	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None of the following	**190 (60.1%)**	**14 (51.9%)**	**204 (59.5%)**
Ablation (of the following)	**4 (1.3%)**	**1 (3.7%)**	**5 (1.5%)**
AV node	0 (0.0%)	1 (3.7%)	1 (0.3%)
HIS bundle	0 (0.0%)	0 (0.0%)	0 (0.0%)
VT	4 (1.3%)	0 (0.0%)	4 (1.2%)
Coronary artery bypass graft(CABG)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery intervention	**110 (34.8%)**	**12 (44.4%)**	**122 (35.6%)**
Balloon angioplasty	46 (14.6%)	4 (14.8%)	50 (14.6%)
Stent	102 (32.3%)	12 (44.4%)	114 (33.2%)
Other	7 (2.2%)	1 (3.7%)	8 (2.3%)
Previous CIED System Implanted	**18 (5.7%)**	**2 (7.4%)**	**20 (5.8%)**
Pacemaker	1 (0.3%)	0 (0.0%)	1 (0.3%)
S-ICD	9 (2.8%)	0 (0.0%)	9 (2.6%)
TV ICD	10 (3.2%)	2 (7.4%)	12 (3.5%)
CRT-P	0 (0.0%)	0 (0.0%)	0 (0.0%)
CRT-D	0 (0.0%)	0 (0.0%)	0 (0.0%)
Days Since Most Recent Explant Procedure			
Mean ± Standard Deviation	42.22 ± 69.06	87.00 ± 2.83	46.70 ± 66.77
Median	13.00	87.00	13.50
25th Percentile - 75th Percentile	7.0 - 56.0	85.0 - 89.0	7.0 - 77.5
Minimum - Maximum	-33.0† - 258.0	85.0 - 89.0	-33.0 - 258.0
Number Of Subjects With Measure Available (N, %)	18 (5.70%)	2 (7.41%)	20 (5.83%)

** Categories in medical history tables may not be mutually exclusive.*

† One subject had their previous CIED system explanted 33 days after enrollment but seven days prior to the EV-ICD implant attempt.

Table 12: Other Medical History

Status	Subjects with EV-ICD Implant Attempted (N = 316)	Subjects without EV-ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None	**204 (64.6%)**	**13 (48.1%)**	**217 (63.3%)**
Asthma	21 (6.6%)	2 (7.4%)	23 (6.7%)
Chronic obstructive pulmonary disease	13 (4.1%)	3 (11.1%)	16 (4.7%)
Chronic bronchitis	3 (0.9%)	0 (0.0%)	3 (0.9%)
Diabetes	66 (20.9%)	8 (29.6%)	74 (21.6%)
Emphysema	0 (0.0%)	2 (7.4%)	2 (0.6%)
Pleural effusion	13 (4.1%)	2 (7.4%)	15 (4.4%)
Renal dysfunction	30 (9.5%)	4 (14.8%)	34 (9.9%)

Table 13: Baseline Medications

Anatomical Group	Medication Type	Subjects with EV-ICD Implant Attempt (N=316)	Subjects without EV-ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
Alimentary Tract And Metabolism	Antacids	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Antiemetics And Antinauseants	3 (2, 0.6%)	0 (0, 0%)	3 (2, 0.6%)
	Ascorbic Acid (Vitamin C), Incl. Combinations	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Blood Glucose Lowering Drugs, Excl. Insulins	78 (55, 17.4%)	8 (4, 14.8%)	86 (59, 17.2%)
	Calcium	7 (7, 2.2%)	1 (1, 3.7%)	8 (8, 2.3%)
	Drugs For Constipation	6 (6, 1.9%)	0 (0, 0%)	6 (6, 1.7%)
	Drugs For Functional Gastrointestinal Disorders	0 (0, 0%)	0 (0, 0%)	1 (1, 0.3%)

Anatomical Group	Medication Type	Subjects with EV-ICD Implant Attempt (N=316)	Subjects without EV-ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD)	97 (96, 30.4%)	4 (4, 14.8%)	102 (101, 29.4%)
	Insulins And Analogues	20 (16, 5.1%)	1 (1, 3.7%)	21 (17, 5.0%)
	Intestinal Anti-inflammatory Agents	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Multivitamins, Combinations	4 (4, 1.3%)	1 (1, 3.7%)	5 (5, 1.5%)
	Other Alimentary Tract And Metabolism Products	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Other Drugs For Acid Related Disorders	5 (5, 1.6%)	0 (0, 0%)	5 (5, 1.5%)
	Other Mineral Supplements	7 (7, 2.2%)	0 (0, 0%)	7 (7, 2.0%)
	Other Plain Vitamin Preparations	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Other Vitamin Products, Combinations	14 (12, 3.8%)	3 (3, 11.1%)	17 (15, 4.4%)
	Potassium	27 (27, 8.5%)	1 (1, 3.7%)	28 (28, 8.2%)
	Propulsives	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Vitamin A And D, Incl. Combinations Of The Two	19 (19, 6.0%)	1 (1, 3.7%)	20 (20, 5.8%)
	Vitamin B1, Plain And In Combination With Vitamin B6 And B12	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
Anti-infectives For Systemic Use	Direct Acting Antivirals	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Other Antibacterials	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Other Beta-Lactam Antibacterials	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Sulfonamides And Trimethoprim	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
Antineoplastic And Immunomodulating Agents	Hormone Antagonists And Related Agents	0 (0, 0%)	1 (1, 3.7%)	1 (1, 0.3%)

Anatomical Group	Medication Type	Subjects with EV-ICD Implant Attempt (N=316)	Subjects without EV-ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Immunosuppressants	13 (9, 2.8%)	0 (0, 0%)	13 (9, 2.6%)
Blood And Blood Forming Organs	Antithrombotic Agents	259 (183, 57.9%)	20 (14, 51.9%)	280 (198, 57.7%)
	I.V. Solution Additives	0 (0, 0%)	1 (1, 3.7%)	2 (2, 0.6%)
	Iron Preparations	9 (9, 2.8%)	0 (0, 0%)	10 (10, 2.9%)
	Vitamin B12 And Folic Acid	12 (11, 3.5%)	0 (0, 0%)	12 (11, 3.2%)
Cardiovascular System	ACE Inhibitors, Combinations	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	ACE Inhibitors, Plain	95 (95, 30.1%)	7 (7, 25.9%)	102 (102, 29.7%)
	Angiotensin II Receptor Blockers (ARBs), Combinations	68 (67, 21.2%)	4 (4, 14.8%)	73 (72, 21.0%)
	Angiotensin II Receptor Blockers (ARBs), Plain	37 (37, 11.7%)	0 (0, 0%)	37 (37, 10.8%)
	Antiadrenergic Agents, Centrally Acting	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Antiadrenergic Agents, Peripherally Acting	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Antiarrhythmics, Class I And III	16 (16, 5.1%)	3 (3, 11.1%)	19 (19, 5.5%)
	Arteriolar Smooth Muscle, Agents Acting On	7 (7, 2.2%)	0 (0, 0%)	8 (8, 2.3%)
	Beta Blocking Agents	239 (236, 74.7%)	14 (14, 51.9%)	254 (251, 73.2%)
	Beta Blocking Agents And Thiazides	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Beta Blocking Agents, Other Combinations	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Cardiac Glycosides	6 (6, 1.9%)	1 (1, 3.7%)	7 (7, 2.0%)
	Diuretics And Potassium-Sparing Agents In Combination	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)

Anatomical Group	Medication Type	Subjects with EV-ICD Implant Attempt (N=316)	Subjects without EV-ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	High-Ceiling Diuretics	113 (110, 34.8%)	8 (8, 29.6%)	123 (120, 35.0%)
	Lipid Modifying Agents, Combinations	6 (6, 1.9%)	2 (2, 7.4%)	8 (8, 2.3%)
	Lipid Modifying Agents, Plain	182 (163, 51.6%)	6 (6, 22.2%)	188 (169, 49.3%)
	Low-Ceiling Diuretics, Excl. Thiazides	3 (3, 0.9%)	0 (0, 0%)	4 (4, 1.2%)
	Low-Ceiling Diuretics, Thiazides	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Other Antihypertensives	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Other Cardiac Preparations	18 (14, 4.4%)	0 (0, 0%)	18 (14, 4.1%)
	Other Diuretics	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Potassium-Sparing Agents	125 (124, 39.2%)	3 (3, 11.1%)	129 (128, 37.3%)
	Selective Calcium Channel Blockers With Direct Cardiac Effects	5 (5, 1.6%)	0 (0, 0%)	5 (5, 1.5%)
	Selective Calcium Channel Blockers With Mainly Vascular Effects	17 (16, 5.1%)	0 (0, 0%)	17 (16, 4.7%)
	Vasodilators Used In Cardiac Diseases	26 (24, 7.6%)	2 (1, 3.7%)	29 (26, 7.6%)
Dermatologicals	Anti-Acne Preparations For Topical Use	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Corticosteroids, Plain	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Other Dermatological Preparations	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)

Anatomical Group	Medication Type	Subjects with EV-ICD Implant Attempt (N=316)	Subjects without EV-ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
Genito Urinary System And Sex Hormones	Androgens	1 (1, 0.3%)	1 (1, 3.7%)	2 (2, 0.6%)
	Drugs Used In Benign Prostatic Hypertrophy	13 (12, 3.8%)	0 (0, 0%)	13 (12, 3.5%)
	Estrogens	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Hormonal Contraceptives For Systemic Use	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Progestogens And Estrogens In Combination	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Urologicals	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
Musculo-Skeletal System	Antigout Preparations	26 (23, 7.3%)	2 (1, 3.7%)	28 (24, 7.0%)
	Antiinflammatory And Antirheumatic Products, Non-Steroids	7 (7, 2.2%)	1 (1, 3.7%)	8 (8, 2.3%)
	Muscle Relaxants, Centrally Acting Agents	4 (4, 1.3%)	1 (1, 3.7%)	7 (6, 1.7%)
Nervous System	Anesthetics, General	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Anesthetics, Local	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Antidepressants	30 (27, 8.5%)	1 (1, 3.7%)	32 (29, 8.5%)
	Antiepileptics	3 (2, 0.6%)	0 (0, 0%)	3 (2, 0.6%)
	Antimigraine Preparations	7 (7, 2.2%)	0 (0, 0%)	7 (7, 2.0%)
	Antipsychotics	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Antivertigo Preparations	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Anxiolytics	11 (11, 3.5%)	1 (1, 3.7%)	12 (12, 3.5%)
	Drugs Used In Addictive Disorders	4 (3, 0.9%)	2 (2, 7.4%)	6 (5, 1.5%)
	Hypnotics And Sedatives	13 (13, 4.1%)	0 (0, 0%)	14 (14, 4.1%)
	Opioids	13 (11, 3.5%)	0 (0, 0%)	13 (11, 3.2%)

Anatomical Group	Medication Type	Subjects with EV-ICD Implant Attempt (N=316)	Subjects without EV-ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Other Analgesics And Antipyretics	27 (25, 7.9%)	0 (0, 0%)	27 (25, 7.3%)
	Psychostimulants, Agents Used For ADHD And Nootropics	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
Respiratory System	Adrenergics For Systemic Use	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Adrenergics, Inhalants	22 (15, 4.7%)	0 (0, 0%)	24 (17, 5.0%)
	Antihistamines For Systemic Use	15 (13, 4.1%)	0 (0, 0%)	15 (13, 3.8%)
	Cough Suppressants, Excl. Combinations With Expectorants	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Expectorants, Excl. Combinations With Cough Suppressants	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Other Drugs For Obstructive Airway Diseases, Inhalants	9 (9, 2.8%)	0 (0, 0%)	9 (9, 2.6%)
	Other Systemic Drugs For Obstructive Airway Diseases	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
Sensory Organs	Antiglaucoma Preparations And Miotics	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins	Anti-Parathyroid Agents	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Corticosteroids For Systemic Use, Plain	6 (6, 1.9%)	0 (0, 0%)	6 (6, 1.7%)
	Thyroid Preparations	16 (16, 5.1%)	0 (0, 0%)	16 (16, 4.7%)
Various	All Other Therapeutic Products	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Homeopathic Preparation	5 (5, 1.6%)	0 (0, 0%)	5 (5, 1.5%)
	Magnetic Resonance Imaging Contrast Media	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Other Nutrients	0 (0, 0%)	1 (1, 3.7%)	1 (1, 0.3%)

Anatomical Group	Medication Type	Subjects with EV-ICD Implant Attempt (N=316)	Subjects without EV-ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Unspecified Herbal And Traditional Medicine	3 (2, 0.6%)	0 (0, 0%)	3 (2, 0.6%)
Total		**1860 (278, 88.0%)**	**102 (17, 63.0%)**	**1981 (297, 86.6%)**

E. Safety and Effectiveness Results

1. Safety Results

Of the 316 subjects that underwent an implant attempt, 23 subjects had a total of 25 major EV-ICD System and/or procedure-related complications through 182 days post-implant.

The freedom from any major EV-ICD System/procedure-related complication through 182 days post implant was estimated using the Kaplan-Meier method. **Table 14** shows that the Kaplan-Meier estimated major EV-ICD System/procedure-related complication free rate through 182 days post implant was 92.6%, with a lower confidence bound of two-sided 95% confidence interval of 89.0%. This was greater than the PG of 79%, hence the primary safety objective was met ($p<0.0001$).

Table 14: Results of Primary Safety Objective

Number of subjects with an implant attempt	Number of subjects with major EV-ICD System/procedure-related complications through 182 days post implant attempt	Kaplan-Meier estimate of major EV-ICD System/procedure-related complication free rate through 182 days post implant attempt	Lower confidence bound of two-sided 95% confidence interval	p-Value
316	23	92.6%	89.0%	<0.0001

Figure 6 is the Kaplan-Meier plot for the freedom from EV-ICD System and/or procedure-related major complications through 182 days post implant. Among the 23 subjects that experienced at least one major EV-ICD System and/or procedure-related complication within 182 days post implant, 15 subjects experienced it within 30 days post implant attempt.

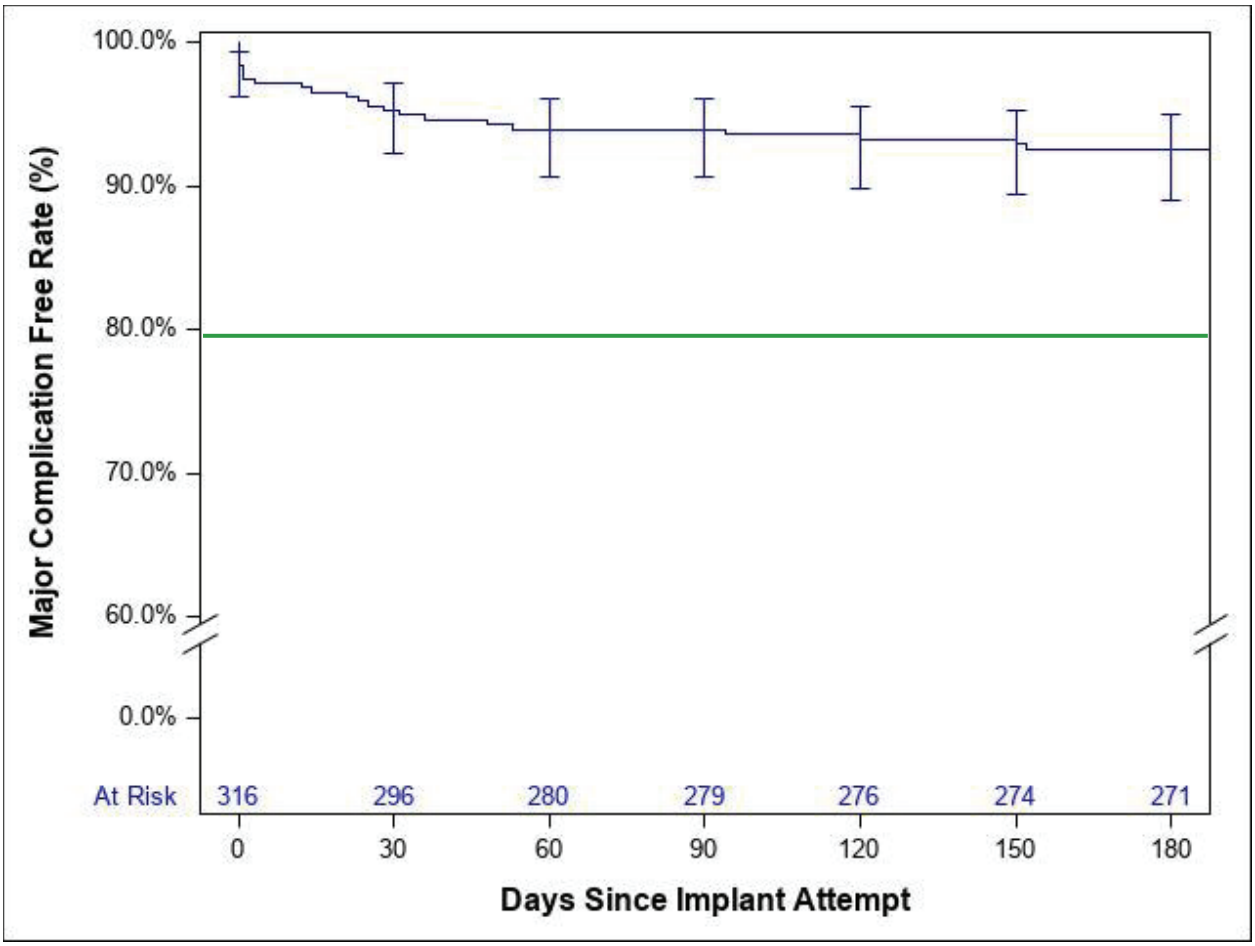


Figure 6: Kaplan-Meier Plot of EV-ICD System/procedure-related Major Complication Free Rate Through 182 Days Post Implant

Figure 7 is the Kaplan-Meier plot for the freedom from EV-ICD System and/or procedure-related major complications through 360 days post implant. The longest follow-up duration among the 299 subjects who underwent an implant attempt without having a major EV-ICD System and/or procedure-related complication was 924 days from implant attempt to the last documented contact.

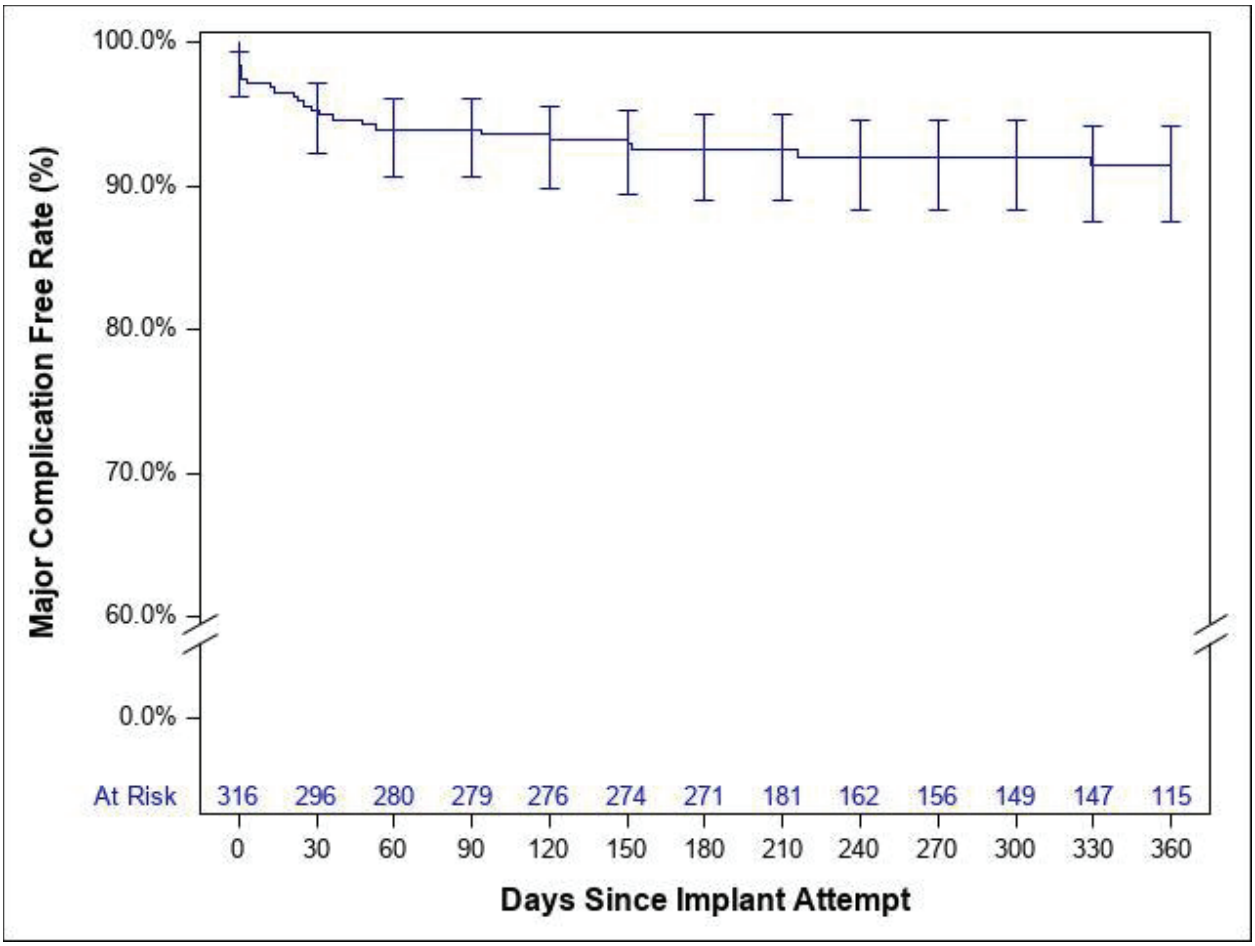


Figure 7: Kaplan-Meier Plot of EV-ICD System/procedure-related Major Complication Free Rate Through 360 Days Post Implant

The cumulative number of subjects with major EV-ICD System and/or procedure-related complications over time are listed in **Table 15**. The EV-ICD System and/or procedure-related major complication free rate estimated by the Kaplan-Meier method was 98.4% at the day of implant attempt, 95.2% at 30 days post implant attempt, and 92.6% from 180 days through 210 days post implant attempt.

Table 15. Major EV-ICD System/procedure-related Complications Free Rate

Days since implant attempt	Cumulative number of subjects with major EV-ICD System/procedure-related complications	Major EV-ICD System/procedure-related complication free rate
0	5	98.4%
30	15	95.2%
60	19	93.9%
90	19	93.9%
120	21	93.2%
150	22	92.9%
180	23	92.6%
210	23	92.6%
240	24	92.0%
270	24	92.0%
300	24	92.0%
330	25	91.4%
360	25	91.4%

A poolability analysis was performed to compare the results of the primary safety endpoint between different geographic regions using a log-rank test. **Table 16** shows that there were no statistical differences in the major EV-ICD System and/or procedure-related complication free rate through 182 days post implant attempt among APAC, EMEA and US/Canada regions (p=0.3330). **Figure 8** is the Kaplan-Meier plot by region.

Table 16: Poolability Analysis of Primary Safety Endpoint on Region

Region	Number of subjects with an implant attempt	Number of subjects with major EV-ICD System/procedure-related complications through 182 days post implant attempt	Kaplan-Meier estimate of major EV-ICD System/procedure-related complication free rate through 182 days post implant attempt (95% CI)	Log-Rank Test p-Value
APAC	37	4	88.9% (73.1%, 95.7%)	0.3330
EMEA	159	9	94.2% (89.2%, 97.0%)	
US/CAN	120	10	91.5% (84.7%, 95.3%)	

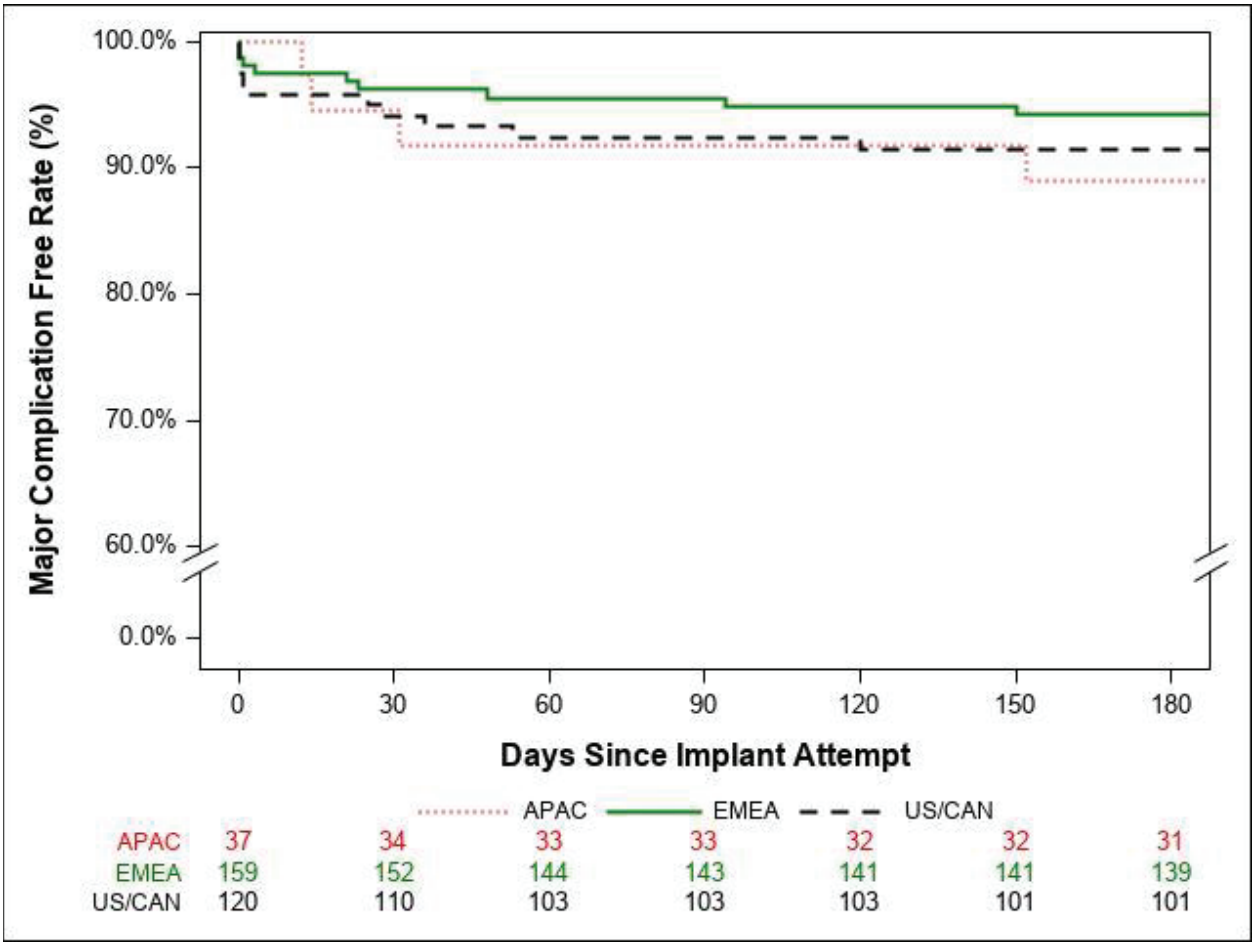


Figure 8: Kaplan-Meier Plot of EV-ICD System/procedure-related Major Complication Free Rate Through 182 Days Post Implant by Region

2. Adverse effects that occurred in the Pivotal clinical study:

In the EV-ICD Pivotal study, the CEC adjudicates Adverse Event (AE) relatedness into Causal Relationship, Possible and Not Related. The CEC also classifies system- or procedure-related AEs into complication (major, minor) or observation. Seriousness of AE and whether an AE is an Unanticipated (Serious) Adverse Device Effect (U(S)ADE) are determined by Medtronic. Adverse events are coded using the MedDRA, Medical Dictionary for Regulatory Activities, which is organized with a five-level hierarchy, The highest or broadest level is System Organ Class (SOC), further divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT), and finally into the most granular Lowest Level Terms (LLT). Preferred Terms (i.e., AE Key Terms) are used in this report.

Table 18 provides a high-level summary of AE seriousness, U(S)ADE, AE relatedness, and complication/observation. All AEs in this report have been evaluated by Medtronic and fully adjudicated by the CEC. Adverse events that were adjudicated by the CEC as Causal Relationship or Possible to the EV-ICD system, to a procedure or to an accessory were regarded as system-, procedure- or accessory-related, respectively. Note that the categories of AE relatedness were not mutually exclusive as an AE could be related to more than one category (e.g., an AE could be system-, procedure- and accessory-related).

There were 756 AEs from 243 enrolled subjects, including 731 AEs from 231 subjects who underwent an EV-ICD implant attempt and 25 AEs from 12 subjects who did not undergo an EV-ICD implant attempt. Among all the adverse events, 331 were serious, three were U(S)ADE, 144 were system- and/or procedure-related (90 procedure-related and 92 EV-ICD System-related), and 31 were accessory-related. Of the 144 system- and/or procedure-related AEs, 50 were complications (27 major and 23 minor complications) and 94 were observations.

Table 17: Overall Summary of Adverse Events

	Number of Events (Number of Subjects, % of Subjects)		
Adverse Event Classification	**Subjects with EV-ICD Implant Attempt (N = 316)**	**Subjects without EV-ICD Implant Attempt (N = 40)**	**Total Subjects (N = 356)**
Serious*			
Yes	318 (164, 51.9%)	13 (8, 20.0%)	331 (172, 48.3%)
No	413 (162, 51.3%)	12 (6, 15.0%)	425 (168, 47.2%)
U(S)ADE**	**3 (3, 0.9%)**	**0 (0, 0.0%)**	**3 (3, 0.8%)**

	Number of Events (Number of Subjects, % of Subjects)		
Adverse Event Classification	**Subjects with EV-ICD Implant Attempt (N = 316)**	**Subjects without EV-ICD Implant Attempt (N = 40)**	**Total Subjects (N = 356)**
Complications/Observations[***]	**144 (108, 34.2%)**	**0 (0, 0.0%)**	**144 (108, 30.3%)**
Complication	50 (45, 14.2%)	0 (0, 0.0%)	50 (45, 12.6%)
Major Complication	27 (25, 7.9%)	0 (0, 0.0%)	27 (25, 7.0%)
Minor Complication	23 (22, 7.0%)	0 (0, 0.0%)	23 (22, 6.2%)
Observation	94 (76, 24.1%)	0 (0, 0.0%)	94 (76, 21.3%)
Relatedness[****]			
System and/or Procedure Relatedness			
Causal Relationship	140 (106, 33.5%)	0 (0, 0.0%)	140 (106, 29.8%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	4 (4, 1.3%)	0 (0, 0.0%)	4 (4, 1.1%)
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	587 (200, 63.3%)	25 (12, 30.0%)	612 (212, 59.6%)
Procedure Relatedness			
Causal Relationship	88 (77, 24.4%)	0 (0, 0.0%)	88 (77, 21.6%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	2 (2, 0.6%)	0 (0, 0.0%)	2 (2, 0.6%)
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	641 (216, 68.4%)	25 (12, 30.0%)	666 (228, 64.0%)
System Relatedness			
Causal Relationship	88 (67, 21.2%)	0 (0, 0.0%)	88 (67, 18.8%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	4 (4, 1.3%)	0 (0, 0.0%)	4 (4, 1.1%)
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	639 (212, 67.1%)	25 (12, 30.0%)	664 (224, 62.9%)

	Number of Events (Number of Subjects, % of Subjects)		
Adverse Event Classification	**Subjects with EV-ICD Implant Attempt (N = 316)**	**Subjects without EV-ICD Implant Attempt (N = 40)**	**Total Subjects (N = 356)**
Accessory Relatedness			
Causal Relationship	6 (5, 1.6%)	0 (0, 0.0%)	6 (5, 1.4%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	25 (23, 7.3%)	0 (0, 0.0%)	25 (23, 6.5%)
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	700 (228, 72.2%)	25 (12, 30.0%)	725 (240, 67.4%)
Total Adverse Events	**731 (231, 73.1%)**	**25 (12, 30.0%)**	**756 (243, 68.3%)**

* AE seriousness collected by investigators and determined by Medtronic.
** U(S)ADE determined by Medtronic.
*** Complications or observations per CEC adjudication for system- or procedure-related AEs.
**** AE relatedness per CEC adjudication; categories of AE relatedness were not mutually exclusive.

Table 18 summarizes system- and/or procedure-related complications by preferred term. There were 50 system- and/or procedure-related complications from 45 subjects with an implant attempt. Of them, 45 complications from 40 subjects were serious. The most common preferred term for complications was lead dislodgement (11).

Table 18. System- and/or Procedure-related Complications by Preferred Term

	Number of Events (Number, % of Subjects with Events) (Denominator = 316 Subjects with Implant Attempt)	
AE Preferred Term	**Event**	**Serious Events**
Lead dislodgement	11 (10, 3.2%)	11 (10, 3.2%)
Postoperative wound infection	5 (5, 1.6%)	4 (4, 1.3%)
Device inappropriate shock delivery	4 (4, 1.3%)	4 (4, 1.3%)
Device inversion	4 (4, 1.3%)	4 (4, 1.3%)
Implant site infection	4 (4, 1.3%)	2 (2, 0.6%)
Chest pain	2 (2, 0.6%)	2 (2, 0.6%)

	Number of Events (Number, % of Subjects with Events) (Denominator = 316 Subjects with Implant Attempt)	
AE Preferred Term	**Event**	**Serious Events**
Device lead damage	2 (2, 0.6%)	2 (2, 0.6%)
Implant site pain	2 (2, 0.6%)	2 (2, 0.6%)
Oversensing	2 (2, 0.6%)	2 (2, 0.6%)
Suture related complication	2 (2, 0.6%)	1 (1, 0.3%)
Device computer issue	1 (1, 0.3%)	1 (1, 0.3%)
Device placement issue	1 (1, 0.3%)	1 (1, 0.3%)
Implant site haemorrhage	1 (1, 0.3%)	1 (1, 0.3%)
Incision site impaired healing	1 (1, 0.3%)	1 (1, 0.3%)
Incision site pain	1 (1, 0.3%)	1 (1, 0.3%)
Medical device site discomfort	1 (1, 0.3%)	1 (1, 0.3%)
Muscle injury	1 (1, 0.3%)	1 (1, 0.3%)
Musculoskeletal chest pain	1 (1, 0.3%)	1 (1, 0.3%)
Postoperative wound complication	1 (1, 0.3%)	1 (1, 0.3%)
Procedural pain	1 (1, 0.3%)	1 (1, 0.3%)
Pulseless electrical activity	1 (1, 0.3%)	1 (1, 0.3%)
Impaired healing	1 (1, 0.3%)	0 (0, 0.0%)
Total	**50 (45, 14.2%)**	**45 (40, 12.7%)**

The three U(S)ADEs included one with device software interaction and three with high-voltage lead fractures. The details are as follows:

3. Device Software Interaction

There was one report of a device computer issue due to previously unknown software-hardware interaction which could cause the high voltage circuit to "lock-up". In this case, following two successful VT/VF defibrillation tests at implant, a subsequent cardioversion was attempted to resolve an atrial arrhythmia. At the time the cardioversion was attempted, the programmer presented an error message indicating the capacitors could not be charged. The device was explanted and replaced without sequelae and an adverse event report was submitted. Due to the rate of occurrence of this issue being higher than anticipated, this event was classified as a U(S)ADE. A clinical communication was disseminated to sites and ethics committees in March 2021 which included programming recommendations to prevent this interaction. Since a malfunction resulting in failure to deliver high voltage therapy

was previously identified as a risk in the protocol and informed consent, there were no changes to the pre-specified risks listed in the study protocol or in the patient's informed consent document. Medtronic developed a software update to permanently eliminate the risk for this interaction. In November 2021, the FDA approved the updated software (v8.3.1), and the software was subsequently provided to subjects globally, following local submissions and approvals as applicable.

4. High-Voltage Lead Fracture

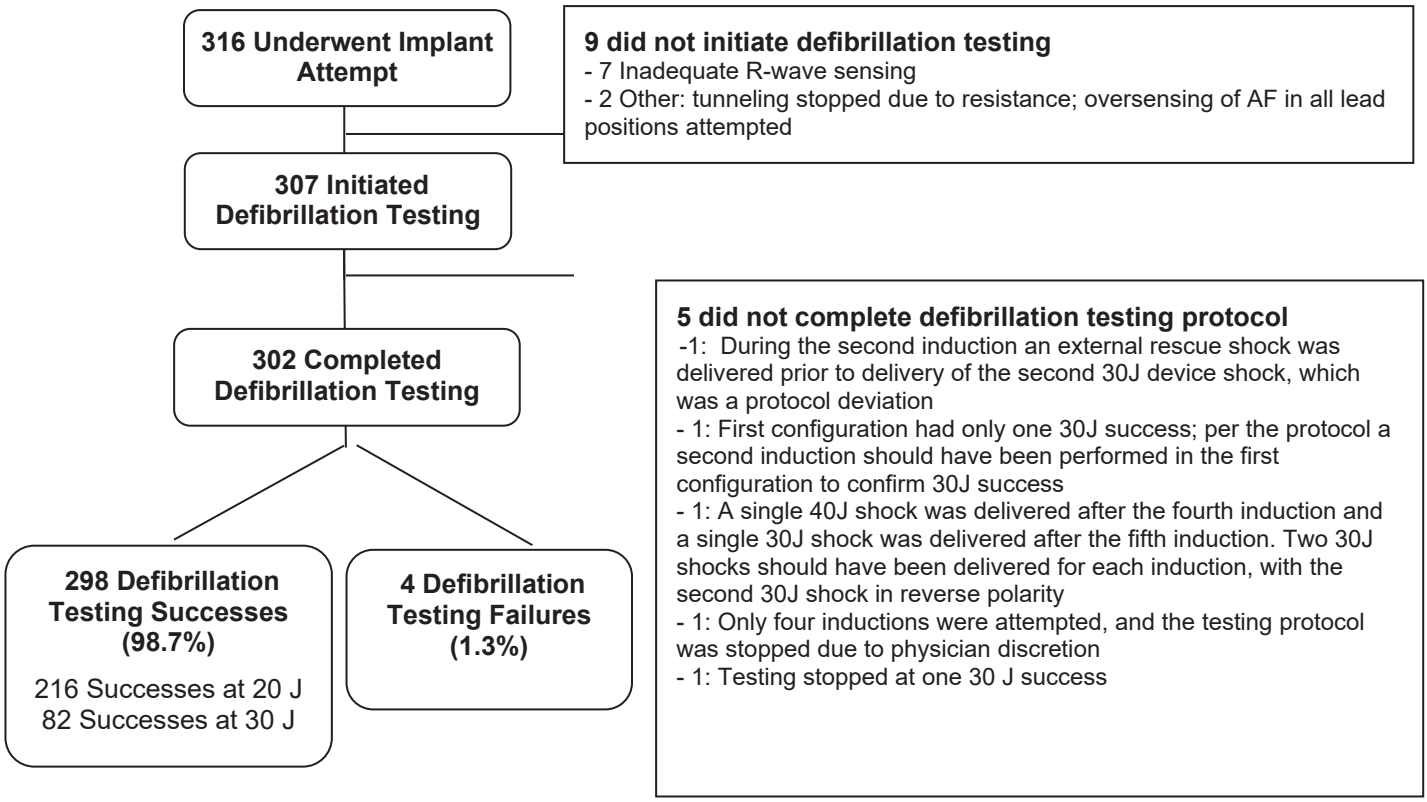
There were two reports of a lead fracture, which were both classified as a U(S)ADEs. In both cases, the fracture was discovered following explant due to a high voltage lead impedance out of range alert. While lead fracture is identified as a potential adverse event associated with the use of this product, these two events were classified as an Unanticipated Adverse Device Effect due to the unanticipated degree of incidence (event occurring within a limited number of implants and early in the lifecycle of the lead). There were no changes to the pre-specified risks listed in the study protocol or in the patient's informed consent document. The location of the lead fracture was the same in both subjects, at the proximal end of the proximal defibrillation coil. After further investigation, it was determined that both fractures were due to excessive lead bending motions, which were not previously observed in pre-clinical or human feasibility studies. Both lead extractions were performed without further clinical sequelae. Notifications were provided (October 2021 and January 2022) to global competent authorities, where required, and Medtronic notified investigating centers and Ethics Committees. There were no new patient management recommendations for previously implanted patients, and physicians were reminded to continue to maintain standard clinical follow-up for patients in the EV-ICD Pivotal Study. At the time of the first communication, enrollments and implants in the Pivotal clinical trial were complete. Subsequent to these observations, updates were made to the lead implant guidance to 1) define the lower limit for lead location to ensure all electrodes are located under (posterior to) the sternum and 2) define the upper limit for lead motion and specify when repositioning should be performed at implant.

NOTE: *There was one additional lead fracture confirmed on a lead explanted from a subject enrolled in the Pivotal study which occurred after the database freeze for this report. This event was classified as a U(S)ADE, bringing the total number of U(S)ADEs to four: one device software interaction and three high-voltage lead fractures. In this case, the patient contacted their clinic to report that their device alarm was sounding, which was 34 months post-implant. The alarm sounded due to a high voltage lead impedance out of range measurement. The patient had a system revision and underwent successful lead extraction and replacement of a new EV-ICD system without sequelae. The fracture was at the connection between the proximal defibrillation coil and the conductor cable. Notifications were provided (January 2023) to global competent authorities, where required, and Medtronic notified investigating centers and Ethics Committees. There were no new patient management recommendations, and physicians were reminded to continue to maintain standard clinical follow-up for patients in the EV-ICD Pivotal Study.*

F. Effectiveness Results

The defibrillation testing status of subjects with an implant attempt is shown in **Figure 9**. Among the 316 subjects with an implant attempt, 9 did not initiate defibrillation testing at implant, 5 did not complete defibrillation testing, and 302 subjects completed defibrillation testing including 298 successes and 4 failures.

Figure 9: Defibrillation Testing Status of Subjects with Implant Attempt



Of the 307 subjects that initiated defibrillation testing at implant, all had at least one ventricular fibrillation (VF) episode that was device-detected in the final lead position at ≥ 0.2mV for the Ring 1 to Ring 2 sensing vector, and all but ten subjects had the defibrillation testing completed on the date of implant.

Table 19 summarizes the implant defibrillation testing status of 316 subjects that underwent an implant attempt. There were 302 subjects who completed the implant defibrillation testing, including 298 successes and 4 failures. Of the 298 subjects with implant defibrillation testing success, 216 (72.5%) had the first SSVA episode terminated successfully with one 20J shock and 82 (27.5%) had two consecutive SSVA episodes terminated with 30J shocks.

Of the 216 subjects that had the first SSVA episode terminated successfully with a 20J shock, 212 subjects had a second SSVA episode tested with a 15J shock including 154 (72.6%) subjects with a 15J success, 58 (27.4%) subjects with a 15J failure. Four subjects were not tested at 15J after a defibrillation success at 20J.

Of the 82 subjects that had two consecutive SSVA episodes terminated with 30J shocks, 68 (82.9%) subjects met this defibrillation criterion after 3 induced SSVA episodes, 7 (8.5%) met it after 4 induced SSVA episodes, 2 (2.4%) after 5 induced SSVA episodes, and 5 (6.1%) after 6 induced SSVA episodes.

Table 19: Implant Defibrillation Testing Status

Implant defibrillation testing status	EV-ICD System fully implanted?	Reason EV-ICD System not fully implanted	Energy level with defibrillation testing success	Number of subjects (Total=316)
Did not initiate implant DFT	N	INADEQUATE R-WAVE SENSING	-	7
Did not initiate implant DFT	N	OTHER: OVERSENSING OF ATRIAL FIBRILLATION IN ALL LEAD POSITION ATTEMPTED.	-	1
Did not initiate implant DFT	N	OTHER: TUNNELING STOPPED DUE TO RESISTENCE	-	1
Initiated implant DFT but did not complete	N	INCOMPLETE DEFIBRILLATION TESTING PROTOCOL	-	4
Initiated implant DFT but did not complete	Y	-	-	1
Completed implant DFT with failure	N	FAILED DEFIBRILLATION TESTING		4
Completed implant DFT with success	Y	-	20J	216
Completed implant DFT with success	Y	-	30J	82

Among subjects who completed the defibrillation testing protocol at implant, the proportion of those who had a defibrillation testing success was 98.7% (298/302), with a lower confidence bound of two-sided 95% confidence interval being 96.6%. This was greater than the PG of 88%, hence the primary efficacy objective was met ($p<0.0001$). Results are summarized in **Table 20**.

Table 20: Results of Primary Efficacy Objective

Number of subjects completed implant DFT	Number of subjects with implant DFT success	Implant DFT success rate	Lower confidence bound of two-side 95% confidence interval	p-Value
302	298	98.7%	96.64%	<0.0001

Table 21 summarizes the number of rescue shocks received among subjects that underwent implant defibrillation testing. Of the 307 subjects that initiated implant defibrillation testing, 156 (50.8%) subjects did not receive a rescue shock, and 151 (49.2%) subjects received at least one rescue shock including:

- 112 subjects had 1 rescue shock
- 21 subjects each had 2 rescue shocks
- 7 subjects each had 3 rescue shocks
- 7 subjects had 4-5 rescue shocks
- 2 subjects had 6-8 rescue shocks (Two subjects with DFT protocol not completed)
- 2 subjects had 10 rescue shocks (One subject with DFT spanned for 3 days to complete the protocol; One subject with DFT protocol not completed)

Table 21: Summary of Number of Rescue Shocks Received

Number of Rescue Shocks Received	Implant DFT Status	Implant DFT Result	Energy Level at Final DFT Success	Number of subjects (Total=307)
0	Completed implant DFT with success	Success	20J	155
			30J	1
1	Completed implant DFT with success	Success	20J	52
			30J	60
2	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
	Completed implant DFT with success	Success	20J	7
			30J	13
3	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
	Completed implant DFT with success	Success	20J	2
			30J	4

Number of Rescue Shocks Received	Implant DFT Status	Implant DFT Result	Energy Level at Final DFT Success	Number of subjects (Total=307)
4	Completed implant DFT with failure	Failure	-	1
	Completed implant DFT with success	Success	30J	1
5	Completed implant DFT with failure	Failure	-	3
	Completed implant DFT with success	Success	30J	2
6	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
8	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
10	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
	Completed implant DFT with success	Success	30J	1

A poolability analysis was performed to compare the results of the primary efficacy endpoint between different geographic regions using a Fisher's exact test. As shown in **Table 22**, there was no significant difference in implant defibrillation testing success rate among APAC, EMEA and US/Canada regions (p=0.7806).

Table 22: Poolability Analysis of Primary Efficacy Endpoint on Region

Region	Number of subjects completed implant DFT	Number of subjects with implant DFT success	Implant DFT success rate	Fisher's Exact Test p-Value
APAC	35	35	100.0%	0.7806
EMEA	154	151	98.1%	
US/CAN	113	112	99.1%	

1. Subgroup Analyses

The cohort included all enrolled subjects who underwent the study procedures unless the subject did not complete the required testing, and there were no pre-specified subgroups for assessment. However, poolability analyses were performed to compare the results of the primary objectives between different geographic regions; no statistically significant differences were observed.

2. Pediatric Extrapolation

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

B. 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 206 investigators of which none were full-time or part-time employees of the sponsor and 8 had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Eight (3.9%) of the investigators had a reportable financial arrangement
- Four (1.9%) investigators received payments exceeding $25,000
- Three (1.5%) investigators reported significant equity interest in Medtronic
- One (0.5%) investigator reported financial arrangements with Medtronic
- No investigators reported that they or their family member has been a part-time or full-time employee of Medtronic

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

A variety of acute feasibility and pilot studies were conducted which contributed data to support of the EV-ICD Pivotal study. These studies did not use the final version of the Aurora EV-ICD System used in the EV-ICD Pivotal Study.

- Acute Substernal Defibrillation (ASD) Study
- Substernal Pacing Acute Clinical Evaluation (SPACE) Study
- Acute Extravascular Defibrillation, Pacing and Electrogram (ASD2) Study
- EV-ICD Pilot Study

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 Circulatory System 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 EV-ICD Pivotal study was a prospective, multi-center, single-arm study that assessed the effectiveness of the Aurora EV-ICD System for treating induced VF at implant in 302 subjects undergoing an implant procedure. Among subjects who completed the defibrillation testing protocol at implant, the proportion of those who had a defibrillation testing success was 98.7% (298/302). Of the successful defibrillation tests, conversion occurred with one 20J shock in 216 subjects, or approximately 73% of subjects; conversion was successful at 15J in 154 subjects, or approximately 50% of subjects. The 95% lower confidence bound of the successful conversion rate in 302 evaluable subjects was 96.6%. The primary efficacy objective was to demonstrate that the defibrillation efficacy at implant of the EV-ICD System exceeds 88%. Therefore, the study met its primary effectiveness objective.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and/or animal studies as well as data collected in clinical studies conducted to support PMA approval as described above. The EV-ICD Pivotal study assessed major complication free rate (CFR) at 182 days post-implant. Major complications included: death, permanent failure of defibrillation therapy due to mechanical or electrical dysfunction of the device, hospitalization, prolongation of an existing hospitalization by at least 48 hours, and system revision. The Kaplan-Meier estimated major EV-ICD System/procedure-related complication-free rate at 182 days post-implant was 92.6%. The 95% lower confidence bound (LCB) was 89.0%, which met the performance goal of > 79%

Of the 316 subjects that underwent an implant attempt, 23 subjects had a total of 25 major EV-ICD System and/or procedure-related complications through 182 days post-implant. System modifications were performed 26 times across 25 subjects, or approximately 6% of subjects. After implant, 92 AEs in 70 subjects were adjudicated as serious and system related, including: Twenty-eight (28) events of inappropriate shock; Eleven (11) events of lead dislodgement; Eight (8) events of chest pain; Five (5) events of medical device site pain. There were three (3) occurrences of lead fracture.

C. Benefit-Risk Determination

The benefits and risks of the Aurora EV-ICD System were demonstrated in acute and long-term clinical studies including the EV-ICD Pivotal IDE study, which was a prospective single arm trial that followed subjects for a minimum of 6 months with over 100 patients followed for a year. The probable benefits of the EV-ICD included the following:

1. The EV-ICD demonstrated effectiveness for terminating induced VF episodes at the time of implant.
2. The EV_ICD also demonstrated effectiveness for terminating induced VF episodes at six-months post implant in a subset of the study cohort.
3. The design of the EV-ICD allows it to be implanted substernally without the need for intravascular lead placement, which may lessen long-term risks seen

in transvenous leads, such as systemic infection involving cardiac structures. The study population was limited to subjects that did not have anatomic or clinical limitations to substernal lead placement; therefore the effectiveness of the EV-ICD system in these patients is unknown.

4. The EV-ICD demonstrated a Kaplan-Meier estimated major EV-ICD System/procedure-related complication-free rate at 182 days post-implant of 92.6%.
5. The defibrillation energy requirement for conversion has been demonstrated to be lower compared to substernal ICD systems, which allows for a smaller ICD generator footprint.
6. The EV-ICD lead location allows for recording of all tachyarrhythmia episodes within a programmed zone, rather than only recording those that result in a shock. In addition, it provides antitachycardia pacing (ATP) and bradycardia pacing for pauses/asystole, albeit with high thresholds compared with transvenous ICD systems, and intolerance due to pain in a minority of patients.

The most common adverse events included lead dislodgement, post-operative wound infection, inappropriate shock, and chest-pain. Post-hoc analysis has related EV-ICD lead dislodgement to either the lead location being placed in the pleural cavity or suboptimal suturing, both of which could be mitigated with training. The inappropriate shock rate at 1 year was comparable to currently available ICD systems. No unique complications that have not been previously described with transvenous ICD or subcutaneous ICD systems have been identified.

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

In conclusion, the data support the use of the EV-ICD in patients who are indicated for an ICD. The benefit of an implanted device that effectively terminates a life-threatening ventricular arrhythmia, restoring normal rhythm, and provides emergency pacing and ATP therapy outweigh the probable risks of the implant procedure and long-term risks of the EV-ICD.

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. The primary safety and effectiveness endpoints in the EV-ICD Pivotal study were both met. The preclinical and clinical testing demonstrated that the design requirements of the device were met. The data provided reasonable assurance through response to induced and spontaneous episodes that the device functioned as intended. Regarding safety, the complication rates and incidence of inappropriate shocks was found to be comparable to that of transvenous and subcutaneous ICDs. Infection and discomfort rates occurred at acceptable levels.

XIV. CDRH DECISION

CDRH issued an approval order on October 20, 2023. The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

The final conditions of approval cited in the approval order are described below:

The Enlighten PAS is a post-market approval registry and will be conducted within the Medtronic Product Surveillance Registry (PSR) platform. Registry data will be collected from patients both US and OUS. The purpose of this study is to confirm the safety and performance throughout the expected lifetime of the Aurora EV-ICD system. The sample size is determined by the effective sample size needed at the timepoint of interest and the patient attrition rate. Minimum enrollment will be 500 patients. Follow up clinical data will be collected at every 6 months and extend out to 10 years.

The primary objective of the PAS will be the following:

1. To demonstrate 5-year Aurora EV-ICD system or procedure related complication-free survival > 79%
    a. The following complications will be included in the analysis:
        i. Death
        ii. Permanent loss of defibrillation function due to mechanical or electrical dysfunction of the device
        iii. Hospitalization
        iv. Prolongation of an existing hospitalization by at least 48 hours
        v. System revision (reposition, replacement, explant)

Ancillary objectives will include the following:

1. To estimate the Aurora EV-ICD System and/or procedure related complication-free survival probability as a function of time post-implant
2. Characterize the rate of abnormal battery depletion complications as a function of time post-implant
3. Summarize all device system revisions (e.g., reposition, replacement, explant) including reasons for modification and action taken
4. Summarize patient deaths
5. Summarize patient demographics and baseline medical history
6. Characterize extracardiac pacing sensation
7. Summarize ATP with spontaneous arrhythmias
8. Characterize asystole pacing
9. Characterize sensing and detection
10. Characterize defibrillation shock effectiveness for terminating spontaneous VT/VF arrhythmia
11. Characterize lead location and lead motion at implant

Care Report Forms will also include the following information and efforts should be made to collect data on as many patients as possible:

1. Characterize the implant procedure (e.g., implant success, total implant time
2. Characterize appropriate/inappropriate shocks
3. Characterize electrical performance over time
4. Summarize MRI-related adverse events
5. Characterize system longevity

A progress report must be submitted every six months for this PAS during the first two years, and annually thereafter. In addition, the results from any surveillance should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement

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

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