P980049

Summary of Safety and Effectiveness Data

Defender II Model 9201

Dual Chamber (ICD) Implantable Cardioverter Defibrillator

P980049

ELA Medical, Inc.
2950 Xenium Lane
Plymouth, MN 55441

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Cardiovascular Respiratory & Neurological Devices

Summary of Safety and Effectiveness Data

Defender II Model 9201 Dual Chamber Implantable Cardioverter Defibrillator

Table of Contents

Summary of Safety and Effectiveness Data

Defender II Model 9201 Dual Chamber Implantable Cardioverter Defibrillator

ELA Medical, Inc.

1 General Information

Device Generic Name:	Implantable Cardioverter-Defibrillator (ICD) System & Programmer
Device Trade Name:	Defender™ II Model 9201 dual-chamber implantable cardioverter-defibrillator and ELA Medical Programmer
Applicant's Name and Address:	ELA Medical, Inc. 2950 Xenium Lane North, Suite 120 Plymouth, MN 55441
PMA Application Number:	P980049
Date of Panel Meeting:	Not Applicable
Date of Notice of Approval to the Applicant:	SEP 15 1999

2 Indications and Usage

The ELA Medical, Inc. Defender II ICD system is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations:

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to ventricular tachyarrhythmia,
- Recurrent, poorly tolerated sustained ventricular tachycardia (VT)

NOTE: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies for this indication have not been studied.

3 Contraindications

Do not use the Defender II in:
- Patients whose ventricular tachyarrhythmias may have transient or reversible causes such as,

- acute myocardial infarction
- digitalis intoxication
- drowning

- electrocution
- electrolyte imbalance
- hypoxia
- sepsis

– Patients with incessant VT or VF,

– Patients who have a unipolar pacemaker,

– Patients whose primary disorder is bradyarrhythmias, or atrial tachyarrhythmias,

– Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction,

– Dual-chamber and single chamber atrial pacing is contraindicated in patients with chronic refractory atrial tachyarrhythmias,

Asynchronous pacing (VOO/AOO) is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

4 Warnings and Precautions

See attached labeling.

5 Device Description

The Defender II ICD system includes the model 9201 ICD pulse generator, other manufacturers' commercially available pacing and defibrillation leads (see *Lead Connections* below) and a computer-controlled programming system.

Physical characteristics: The Defender II ICD has a hermetically-sealed titanium case and a silicone elastomer (medical grade) connector head.

- Volume: 75 cc
- Dimensions: 84.9 mm x 60 mm x 19 mm
- Weight: 140 g

Waveform: The output defibrillation waveform configuration is biphasic (a positive phase and a negative phase) with a maximum stored energy of 33 Joules (J) that can be delivered as either constant-tilt or constant-width. Constant-tilt shocks have 50% tilt in each phase; and constant-width shocks have a 5 millisecond width in each phase.

Features and Functions: The Defender II is designed to recognize and treat VT and VF (ventricular fibrillation) by continuously monitoring atrial and ventricular activity to identify persistent ventricular arrhythmias and automatically deliver appropriate programmed therapies. The ELA ICD system features an arrhythmia detection system known as the PARAD™ algorithm. It is specifically designed to differentiate ventricular tachycardias from fast rhythms of supraventricular origin. The device continuously monitors R-R interval stability, assesses the degree of P-R association and tracks the chamber from which an acceleration originates.

In addition to the PARAD™ detection scheme, the Defender II offers programmable dual- or single-chamber pacing therapy (DDD, DDI, or VVI modes). Like other ICDs of the present generation, Defender II offers a multi-tiered therapy scheme. There are two independent ATP (antitachycardia pacing) programs, one cardioversion (for VT) program, and two defibrillation (for VT/VF) programs.

Other features are as follows:

- Automatic ventricular sensing threshold control
- Automatic capacitor reforming

- Non-committed shocks
- 5 to 7 year longevity (assuming 15% pacing and four 33 J shocks per year)
- Electrophysiological studies (EPS) with real-time markers or electrograms
  - Programmer-controlled VT induction sequences
  - Programmer-controlled VF inductions (30 Hz rapid pacing or shock on T)
  - V (ventricular) or V-A (ventricular minus atrial) electrogram options
  - Real-time annotations indicating the majority rhythm within the marker option
  - Manual ATP sequences
  - Manual shocks
- Rescue shock
- Automatic follow-up tests
  - Defibrillation electrode continuity
  - Charge time for the shock capacitors
  - Pacing lead impedance
  - Automatic pacing threshold tests
- Data storage
  - Therapy History Report
  - Statistics
    - Pace/sense statistics
    - Therapy statistics, including untreated arrhythmias
    - Shock statistics
    - Last charging and last shock statistics
    - Battery voltage over time, since beginning of life
  - Up to five complete Holter records with zoom to view the following:
    - Event summaries for up to 31 discrete events before and during therapy, each providing number of paced and sensed events per minute, along with arrhythmia detection, ATP and shock information
    - Marker chain and electrogram snapshots of arrhythmia onset and conversion with cursors for measuring intervals and amplitudes

Lead Connections: The connector head has four ports: atrial bipolar pace/sense, ventricular bipolar pace/sense, and two for defibrillation shocks (one positive, one negative). Both pace/sense ports are compatible with the IS-1 standard; and both defibrillation ports are compatible with the DF-1 standard. Lead terminal connections are secured with set-screws accessed via self-sealing silicone plugs. Pacing pulses, shocks and sensed signals pass to and from the case via ceramic feedthroughs. The following high voltage and defibrillation leads were used during the clinical study (N=number of patients) and are compatible with the Defender II Model 9201 ICD.

Manufacturer	Model (n)	Placement	Fixation
Biotronik	SL-ICD (56)	RV and SVC coils	Tines
	SPS (13)	RV	Tines
Guidant	Endotak 0048 (1)	RV and SVC coils	Tines
	Endotak 0072 (3)	RV and SVC coils	Tines
	Endotak 0095 (9)	RV and SVC coils	Tines
	Endotak 0125 (3)	RV and SVC coils	Tines
	Endotak (Model Unk. 4)	RV and SVC coils	Tines
Medtronic	Sprint 6932 (1)	RV	Tines
	Sprint 6942 (36)	RV and SVC coils	Tines
	Sprint 6943 (4)	RV	Extendable Screw
	Sprint 6945 (1)	RV and SVC coils	Extendable Screw

Programming System: The ELA Medical programmer is a small portable computer that is used in conjunction with specific programmer software to interrogate and program the implanted Defender II pulse generator at implant and during patient follow-up procedures. The CPR1D programming head is used to establish communications with the pulse generator.

6 Alternative Practices or Procedures

Alternative therapies for the treatment of life-threatening ventricular arrhythmias, as deemed appropriate by the physician based upon electrophysiology (EP) testing and other diagnostic evaluation, include the use of antiarrhythmic medication, electrical ablation and cardiac surgery, electronic devices including pacemakers and other commercially available implantable defibrillators, or a combination thereof.

7 Marketing History

The Defender II has not been withdrawn from the market in any country for any reason related to the safety and effectiveness of the device and is currently marketed in the following countries: France, Germany, Belgium, Great Britain, Italy, Sweden, Greece, Spain, Turkey, and Argentina.

8 Adverse Events

Reported Adverse Events

Clinical study of Defender 9001 and Defender II 9201 included 167 devices implanted in 167 patients worldwide. Ninety-five patients were implanted with Defender 9001; 72 patients received Defender II. Both devices operated identically, however, Defender 9001 was intended for abdominal implant only and Defender II was implanted pectorally. Defender 9001 is only intended for market outside of the U.S. Implant duration ranged from 0 to 40.6 months with an average of 13.6 months. Total device exposure was 2,277 device months. No deaths, serious adverse experiences or complications were judged to be device-related, as determined by an independent physician advisory committee. Table 1 summarizes the safety data for this study.

Table 1. Summary of Safety Data

	Defender 9001 Europe (n=95)			Defender II Europe (n=33)			Defender II U.S. (n=39)			Total U.S. & Europe (n=167)		
	No. of events	Patients		No. of events	Patients		No. of events	Patients		No. of events	Patients	
		N	%		N	%		N	%		N	%
Deaths	12	12	12.6	1	1	3.0	2	2	5.1	15	15	9.0
Explants	12	12	12.6	0	0	0	0	0	0	12	12	7.2
Complications	50	30	31.6	2	2	6.1	2	2	5.1	54	34	20.4
Observations	104	55	57.9	16	12	36.4	7	7	17.9	127	74	44.3
Serious, not related	73	44	46.3	12	9	27.3	2	2	5.1	87	55	32.9

There were a total of 15 deaths in the study, two of which were classified as sudden cardiac death; all were reviewed by an independent physician advisory committee. Thirteen of these deaths occurred more than one month post-implant. Causes of death are presented in Table 2. Causes of explant (7.2%) are presented in Table 3.

Table 2. Causes of Death

All deaths (15 of 167 patients)

Cause of Death (n = 15)	# of Patients	Time After Implant (Months)
Heart Failure/Pulmonary Edema	8	0, 39,14,7.5, 5.5, 5, 3, 0.5
Sudden Cardiac Death	2	2.5, 31
Acute Myocardial Infarction	1	7
Electromechanical Dissociation	2	9,6
Non Cardiac: Gastric Bleeding, Intestinal Infarction	2	17.5, 7.5

Table 3. Causes of Explants

All explants, 12 of 167 patients

Cause of Explant (n = 12)	# of Patients	Time After Implant (Months)
Heart Transplant	3	7.5, 12.5, 10.5
Device Migration/Exteriorization/Tissue Erosion	3	20, 13, 10
Device Reset	1	15.5
Endocarditis	1	4.5
Infection/Pocket Infection/Device Migration	2	13.25, 13
Lead Malfunction, Ventricular	1	19
Worsening Rhythm Disorder	1	23

In the following tables, complications are defined as adverse events requiring invasive measures to correct, e.g. surgical revision and observations are defined as adverse events that are correctable by noninvasive measures, e.g. reprogramming. Table 4 presents an overview of complications/observations attributed to the ICD system and/or implant procedure for Defender 9001 and Defender II 9201, respectively. Tables 5 and 6 provide complications and observations for Defender II 9201 exclusively.

Thirty of the 95 Defender 9001 patients (abdominal implant) experienced a total of 50 complications, including device failures and replacements. Fifty-five of the 95 Defender 9001 patients experienced a total of 104 observations. Some have already been reported in Tables 2 and 3.

Table 4. Overview of Clinical Complications and Observations During Study

All patients (n=167)

Event	Device	Patients with Events	% of Patients	95% Exact C.I.	# of Events	Events/100 Device Years
Complications	Defender 9001	30/95	31.6	22 – 42	50	34
Observations	Defender 9001	55/95	57.9	47 – 68	104	70
Complications	Defender II	4/72	5.6	1.5 – 14	4	9.5
Observations	Defender II	19/72	26.4	17 – 38	23	55

Table 5. Summary of Clinical Complications (Including Device Failures and Replacements)

All complications, 4 of 72 Defender II patients

Event	# of Patients	% of Patients	# of Events	Events/100 Device-Years*
Any complication	4	5.6	4	9.508
Absence of therapy for VT below VT rate zone	1	1.4	1	2.377
Incomplete ventricular lead connection	1	1.4	1	2.377
Ventricular lead blood infiltration	1	1.4	1	2.377
Ventricular lead replacement due to VF undersensing at implant	1	1.4	1	2.377

*Event rate per 100 device-years is calculated as the number of events multiplied by a factor, 2.377. This factor is equal to 100/total device-years. In these data, 72 patients had a total of 42.067 device-years.

Table 6. Summary of Clinical Observations (Including Patient Complaints)

All observations, 19 of 72 Defender II patients

Event	# of Patients*	% of Patients	# of Events	Events/100 Device-Years**
Any observation	19	26.4	23	54.671
Absence of therapy on slow non-sustained VT	1	1.4	1	2.377
Absence of VT therapy	2	2.8	2	4.754
Atrial undersensing	2	2.8	2	4.754
Atypical chest pain	1	1.4	1	2.377
Elevated ventricular threshold, decreased ventricular amplitude	1	1.4	1	2.377
EMI, suspected	1	1.4	1	2.377
Hematoma	1	1.4	1	2.377
Inappropriate ATP	2	2.8	2	4.754
Inappropriate shock	4	5.6	4	9.508
Ineffective ATP therapy	1	1.4	1	2.377
Multiple painful ICD shocks	1	1.4	1	2.377
Pneumothorax	1	1.4	1	2.377
Programmer software malfunction	1	1.4	1	2.377
Thrombus	1	1.4	1	2.377
VF therapy for ST in VF rate zone	1	1.4	1	2.377
Wound dehiscence	1	1.4	1	2.377
Wound infection	1	1.4	1	2.377

*Some patients experienced more than one type of observation.

**Event rate per 100 device-years is calculated as the number of events multiplied by a factor, 2.377. This factor is equal to 100/total device-years. In these data, 72 patients had a total of 42.067 device-years.

Potential adverse events

Adverse events (in alphabetical order), including those reported in the previous tables, associated with ICD systems include:

- Acceleration of arrhythmias (caused by device)
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

9 Summary of Preclinical Studies

9.1 Laboratory Studies

Non-clinical testing consisted of bench testing to ensure that the components and the finished device perform in accordance with their design specifications. This involved components, subassemblies, finished devices, and software. The manufacturer also conducted manufacturing-process validation studies (SeeTable 7. Summary of Laboratory Testing).

Component and subassembly tests

The manufacturer used certain tantalum and ceramic capacitors previously qualified for use in its cardiac pacemakers. Component qualification tests were conducted for all new components. All tests demonstrated that these components were qualified for use in the implantable defibrillator.

Finished-device tests

Qualification included both verification and validation testing. Functional, electromagnetic interference, mechanical, and packaging tests were performed as shown in the table above. All tests demonstrated that the defibrillator and its packaging were qualified for their intended use.

Software validation

Programmer and implantable-defibrillator software (CSO 1.00.09) underwent validation testing. This included review of formal requirements and design documents, a general system hazard analysis, and functional validation testing following a formal validation plan. The manufacturer also conducted an analysis of the use of an off-the-shelf operating system for the programmer. A library of tape-recorded arrhythmias was also used to evaluate the diagnostic accuracy of the defibrillator's arrhythmia-detection algorithm. Software validation demonstrated that the programmer and implant were qualified for their intended use. ELA is currently developing a custom-designed and built dedicated programmer for which it intends to seek approval. ELA expects this dedicated programmer eventually to replace the current system.

Process validation

The manufacturer conducted process-validation studies on processes not fully verifiable by subsequent inspection and test. This included the laser-welding process for the defibrillator case, and the finished-device sterilization process. These studies determined that the processes were qualified for production of implantable devices.

Biocompatibility

The biocompatibility of materials in tissue contact in the defibrillator has been well established by use in this and other manufacturers' cardiac pacemakers. These materials include titanium and silicone rubber. There were no new materials or processes introduced with Defender II that would raise new issues of biocompatibility.

Table 7. Summary of Laboratory Testing

Test Performed	Sample Size	Test Results (pass/fail)
Electrical qualification testing		
Components		
Hybrid substrate: life test 1000h at 125C	22	PASS
Ceramic Capacitors: initial electrical measurements, 1000 hr burn-in at 125C, final electrical measurements	100	PASS
Tantalum Capacitors: initial electrical measurements, voltage aging, life test, thermal cycling, thermal strength	10-140	PASS
Chip inductors: solderability, resistance to solvents, thermal cycling, electrical continuity, visual inspection, resistance to solvents, electrical properties, overload	4-8	PASS
Resistor chips: visual inspection, dimensional inspection, electrical tests, shear-strength, solderability	20	PASS
Microprocessor life tests	10	PASS
Battery qualifications	5	PASS
Diodes: Dimensional inspection, thermal cycling, electrical tests, burn-in, visual inspection, life tests	2-100	PASS
Other components: packaging and dimensional inspection, electrical tests, burn-in, visual inspection, life tests	47-150	PASS
Finished devices		
Temperature in use, EMI-induced current, induced malfunction, interference, sensing effect, static magnetic fields, telemetry distance, protection from electrosurgery, ultrasound, EAS, ESD, cellular telephones	1-2	PASS
Internal gas analysis	3	PASS
Postshock pacing recovery, pacing/shock short circuit, DC/AC leakage current, internal defibrillation, external defibrillation, life test	5	PASS
Sterilization: peel test, insertion/rotation test, immersion test, marking resistance	39	PASS
Mechanical qualification testing		
Connector assembly		
Visual dimensional, conditioning, nominal and maximal IS-1 insertion/extraction, nominal and maximal DF-1 insertion/extraction, pacing and defibrillation circuit impedance, electrical isolation prior to aging, torque wrench insertion, tightening/loosening of setscrews, tilting of torque wrench	5	PASS
Impedance variation under stress, electrical shocks in defibrillation circuits, sample conditioning, electrical isolation, pacing impedance	2	PASS
Tightening of suture knot, pacing and defibrillation lead	3	PASS

Test Performed	Sample Size	Test Results (pass/fail)
perforation, adherence between connector and case		
Hermetic feedthrough		
Electrical isolation resistance, hermeticity, soldering/unsoldering, tensile strength, bending, compression, laser welding, thermal shock, drop test, high intensity current, aging	5	PASS
Titanium oxidation	1	PASS
Environmental (packaged and unpackaged)		
Insertion/extraction of leads, mechanical shocks, telemetry, pressure changes, marking resistance, compression, vibration, gas analysis, conditioning, dynamic compression, drop test, shock, localized bending, perforation, temperature cycling, hermeticity, bioburden	2-8	PASS
Programmer		
Safety testing		
Leakage current through housing, AC/DC auxiliary current, breakdown voltage, mechanical resistance, emissions, immunity	1	PASS
Environmental testing		
Temperature, humidity, atmospheric pressure for transport and storage; ambient temperature, humidity, atmospheric pressure for normal use; vibration, shock (drop), emission of radio frequencies, immunity to electromagnetic fields, electrostatic discharge, transients/bursts	1	PASS
Embedded software		
Source code verification, binary code comparison, detection, therapy, redetection, ERI/EOL behavior, holter and memory functions, pace/sense counter, shock capacitor formation, induction verification, functional testing	Current version of embedded software	PASS
Animal studies (see 9.2 below)		
Canine only	14	PASS
Canine and sheep	2 dogs, 1 sheep	PASS

9.2 Animal Studies

Acute animal studies to evaluate the performance of a predecessor device for abdominal implant were conducted in fourteen dogs under three protocols between 1992 and 1995. Any device issues observed were corrected before the first human implant in 1995. Acute animal studies involving two dogs and one sheep were conducted with Defender II. No device issues were observed.

9.3 Additional Studies

Additional EMI testing was performed by an independent contractor. The results of these radiated E-field tests demonstrated no interference with the Defender II ICD.

10 Summary of Clinical Studies

10.1 Objectives

The primary objectives of this study were to determine ventricular arrhythmia termination success rates and specificity of the PARAD™ (P- and R-arrhythmia detection) algorithm in differentiating VT from rhythms of supraventricular origin, such as supraventricular tachycardia (SVT) and sinus tachycardia (ST).

Primary endpoints: The sponsor sought to demonstrate, at 95% confidence:

- ≥ 98% VF termination success,
- ≥ 95% of spontaneous VT termination success and
- ≥ 85% specificity in rejecting spontaneous SVT/ST.

Patients underwent standard ICD implantation and were evaluated at predischarge, and at 1, 3, and 6 months post implant and every 3 months thereafter.

10.2 *Background*

Data were collected prospectively under controlled studies in Europe and the United States (U.S.). All Defender II 9201 data collected in the U.S. under the IDE (G970282) were pooled with European Defender 9001 and Defender II 9201 data to test each of the hypotheses for the primary objectives and to determine safety of the device. Comparability and poolability of the two patient populations was evaluated for the primary hypotheses as shown in Tables 8, 9 and 10.

One hundred twenty-eight patients were enrolled at 35 institutions in Europe and 43 patients were enrolled at seven institutions in the U.S. in this non-randomized, prospective study. Clinical data are presented here for 167 of those patients; data from four of the U.S. patients have not been analyzed due to their recent implant dates. Ninety-five patients were implanted with Defender 9001; 72 patients received Defender II 9201. Both devices operated identically, however, Defender 9001 was intended for abdominal implant only and Defender II was implanted pectorally.

The U.S. investigation was conducted using Medtronic® Sprint™ passive fixation leads (Model 6932 or Model 6942). However, two patients received active fixation leads due to their physiological condition at implant. These patients are included in the study analysis.

The U.S. IDE study's routine evaluation of the Defender II consisted of pre-implant screening, implant, pre-discharge evaluation, and scheduled follow-up visits at 1, 3, 6, and every 3 months thereafter. Unscheduled follow-up visits, deaths, explants, and patients lost to follow-up were also documented. Spontaneous events such as VF, VT and SVT (supraventricular tachycardia) were captured by Defender II's internal Holter and documented at scheduled or unscheduled follow-up visits.

10.3 Results

The patients (147 M / 20 F) had a mean age of 61.4 (range 18 to 87) years and a left ventricular ejection fraction of 35.0% (10% to 75%) (n = 141). The primary indication for implant was ventricular tachycardia in 107 (64.0%), ventricular fibrillation in 50 (30.0%), ventricular tachycardia and ventricular fibrillation in 8 (4.8%), syncope in 1 (0.6%) and 1 (0.6%) other. Cardiovascular history included cardiomyopathy (29.3%), other coronary disease (91.6%),

hypertension (23.4%), heart failure (37.3%), and valvular disease (17.4%) (non-exclusive categories).

Table 8. VF comparability and pooling

Attribute	No. of Patients	VF Termination Success Rate (%)
Male	118	100
Female	18	100
Small Centers (<4 patients)	36	100
Large Centers (>4 patients)	100	100
Europe	97	100
USA	39	100
Defender 9001	67	100
Defender II 9201	69	100

Table 9. VT comparability and pooling

Attribute	No. of Episodes	No. of Patients	VT Termination Success Rate (%)
Male	401	52	98.5
Female	15	6	100
Small Centers (<4 patients)	78	21	98.7
Large Centers (>4 patients)	338	37	98.5
Europe	378	50	98.4
USA	38	8	100
Defender 9001	334	41	98.5
Defender II 9201	82	17	98.8

Table 10. SVT/ST comparability and pooling

Attribute	No. of Patients	Observed freedom from spurious treatment (%)
Male	147	91.2
Female	20	85.0
Small Centers (<4 patients)	54	88.9
Large Centers (>4 patients)	113	91.2
Europe	128	87.5
USA	39	100
Defender 9001	94	85.3
Defender II 9201	72	97.2

Study inclusion and exclusion criteria were designed and the study was carried out to avoid gender bias in patient enrollment. The exception to this was the exclusion of pregnant women. Overall, 11.98% of the patients included in the clinical investigation were female. Table 11 demonstrates that results were similar with respect to freedom from spurious treatment, ventricular tachycardia and ventricular fibrillation.

Table 11. Gender Bias Analysis in Primary Endpoints

All patients (n = 167)

Parameter	Male n=147	Female n=20
Freedom from spurious treatments	91.2%	85.0%
VT Termination	98.5%	100.0%
VF Termination	100.0%	100.0%

Mean defibrillation threshold was 9.5J. The following table demonstrates that all three objectives of this study were successfully met. Overall cumulative survival rate at one year was 92%.

Table 12. ICD Clinical Study Results

All patients (n = 167)

Parameter	Sample	Observed successes	Observed success rate %	95% Exact CI
	Patients	136/136	100	97.8 –100
	Spontaneous Episodes	31/31	100	90.8 – 100
VT Termination	Patients	55/58	94.8	85.6 - 98.9
	Episodes	410/416	98.6	96.9 - 99.5[1]
SVT Untreated	Patients	151/167	90.4	84.9 - 94.4
	Episodes	475/526	90.3	87.8 - 92.7

10.5 Device Failures and Replacements

No device failures or replacements occurred with Defender II during the study.

11 Conclusions Drawn from the Studies

It is reasonable to conclude that the benefits of use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use.

The manufacturer conducted risk analyses and identified risk control measures for hardware, defibrillator software, and programmer software, and then conducted testing to evaluate these and other device features. The hybrid subassembly, electronic subassembly, and finished device were subjected to stresses designed to simulate or exceed device use. Defibrillator and programmer software was tested functionally. The device passed all these in-vitro tests. The in-

[1] 96.7 – 100 % after adjustment for statistical dependence of episodes in the same patient.

vitro testing, animal testing and clinical studies provide reasonable assurance that the Defender II ICD system is safe and effective, when used as indicated in the labeling.

12 Panel Recommendation

Pursuant to the provisions of section 515(c)(2) of the Food, Drug and Cosmetic Act (FD&C) as amended by the Safe Medical Devices Act of 1990 (SMDA 1990), this PMA application was not referred to the Circulatory System Devices Panel, an FDA advisory panel committee, for review and recommendation because the information in the PMA application substantially duplicates information previously reviewed by this panel.

13 FDA Decision

Based on the reviews of the original PMA application and its amendments, FDA determined that the device provides reasonable assurance of safety and effectiveness when used as indicated in the labeling. FDA found ELA Medical manufacturing facility to be in compliance with the Device Quality System Regulation (21 CFR part 820).

14 Approval Specifications

Directions for use: See the labeling.

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

Post-approval Requirements and Restrictions: See approval order.

The Approval Order, Summary of Safety and Effectiveness Data, and labeling can be found on the Internet at http: //www.fda.gov/cdrh/pmapage.html.