Summary of Safety and Effectiveness Data

P010030

Lifecor, Inc.

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Pittsburgh, PA 15238

WCD® 2000 System

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Cardiovascular and Respiratory Devices
Pacemaker Defibrillator and Leads Branch

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I. General Information

Device Generic Name:	Wearable Cardioverter Defibrillator
Device Trade Name:	WCD® 2000 System
Applicant's Name:	LIFECOR Inc. 121 Freeport Rd. Pittsburgh, PA 15238
PMA Number:	P010030
Date of Panel Meeting:	Not applicable
Date of notice of approval to applicant:	Dec. 18, 2001

II. Indications for Use

The Lifecor Wearable Cardioverter Defibrillator, or WCD® 2000 System, is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.

III. Contraindications

The WCD® 2000 System is contraindicated for use in patients with an active implantable defibrillator.

IV. Device Description

The LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 system is an automatic external defibrillator system. It is comprised of the WCD® 2000 device that consists of the wearable components of the WCD® 2000 system, i.e., the Monitor, Battery Pack, Alarm Module, Electrode Belt, Garment, and Holster. The non-wearable components include the Battery Charger, the Modem, the Modem Cable, the Computer Cable, the WCDNET and the Diagnostic Tester. A schematic of selected WCD® components is shown below in Figure 1. Table 1 provides a brief description of each component.

The WCD® 2000 is a microprocessor-based and programmable patient-worn device that is designed to sense cardiac function and automatically deliver electrical therapy to treat

ventricular tachyarrhythmias. The device is to be worn continuously by the patient, as its purpose is to continuously monitor the patient's electrocardiogram (ECG) and to detect life-threatening ventricular tachyarrhythmias, specifically, ventricular tachycardia (VT) and ventricular fibrillation (VF). If the WCD® 2000 device detects VT or VF above a programmable pre-set rate, it is capable of delivering a defibrillating pulse to the heart through the therapy electrodes in an attempt to restore an effective rhythm.

The device communicates with the patient through voice and display messages, tones or alarms and vibration of a stimulator against the skin. When the device detects an arrhythmia, it also instructs the patient to stop the impending shock by pressing the response buttons to avoid receiving a shock while conscious because of the pain associated with the shock. If a patient receives a shock while conscious, there is a small possibility that an abnormal heart rhythm can be induced by an unsynchronized shock that may not be detected by the device.

It usually requires 15 to 25 seconds to identify a malignant arrhythmia. The WCD® 2000 is designed to automatically deliver electrical shock therapy pulse within 60 seconds from the onset of a VT/VF unless a conscious patient presses the response buttons. It can deliver up to 5 defibrillating pulses during an arrhythmic episode. The physician can program the energy of the pulses to be between 50 and 280 joules. The WCD® 2000 device also records the patient's ECG, allowing playback of arrhythmic events for physician review.

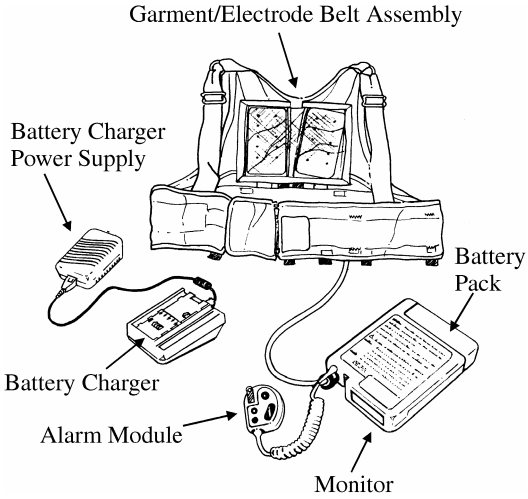

Figure 1. Selected WCD® Components

A secure web-based data storage and retrieval system known as WCDNET allows physicians to access patient data stored in the Patient Database using a web browser and Internet connection. Only authorized users registered by LIFECOR and a password and can access WCDNET. In addition, the data transferred over the Internet is encrypted. An authorized physician or operator can view and print ECG events and generate reports related to patient wear time compliance and overall WCD® 2000 monitoring performance.

Table 1. WCD® 2000 System: WCD® 2000 Device (Wearable Components) and Non-Wearable Components

WCD® 2000 Device Wearable Component	Description
Monitor and Alarm Module	The WCD® 2000 Monitor contains the diagnostic circuitry and the defibrillation circuitry. A liquid crystal display (LCD) provides status information and instructions to the patient or operator. The electrode belt and battery pack are attached to the monitor, and an expansion port connector is used for programming the monitor with patient's information and programmable parameters, and transferring data to WCDNET. A permanently attached Alarm Module clips onto the patient's belt or shirt pocket. It is designed to alert the patient to certain conditions through lights and voice messages.
Battery Pack	The Battery Pack is a rechargeable power source that attaches to the monitor and when depleted, the patient removes it by sliding the release latch and removing it, and replacing it with a fully-charged Battery Pack.
Electrode Belt	The Electrode Belt consists of the ECG monitoring electrodes, a grounding electrode with a tactile stimulator, and the therapy electrodes, all interconnected by electrical wiring. Four ECG monitoring electrodes are designed to provide continuous body-surface ECG monitoring. Three therapy electrodes are designed to deliver the cardioverting/defibrillating energy through the patient's chest. A small quantity of electrolytic gel is contained in each of the electrodes, and is dispersed when treatment is required.
Garment	The Garment is worn under the patient's clothing next to the skin. It is designed to position the electrodes and therapy pads against the patient's chest.
Holster	The Holster is designed to hold the Monitor on the patient's body.

Non-wearable Component	Description
Battery Charger	The Battery Charger is designed to charge the Battery Pack after 24 hours of use, and has lights and symbols to indicate its status.
Modem cable and Modem	A telephone modem and a connecting cable are provided to each patient to allow recorded information to be sent for review by the physician. The modem connecting cable is connected to the expansion port on the monitor. Recorded information including ECG data, compliance data, and other device performance data is then sent automatically to a communications server.
WCDNET	A secure, Lifecor, Inc. internet website that maintains patient information.
Computer cable and Diagnostic tester	The physician uses this equipment for programming and device testing. A personal computer is used with the computer cable to set programmable values for each patient, including rate thresholds and energy levels.

V. Warnings and Precautions

See attached labeling.

VI. Alternative Practices and Procedures

The following are several alternative practices and procedures to the WCD® 2000 device:

- *Sudden Cardiac Arrest Treatment by Emergency Medical Services, EMS, or Calling 911*. Paramedics are trained to diagnose countershock or defibrillation-reversible conditions and apply such therapy if needed.
- *Automatic External Defibrillators (AEDs) in the Community*. AEDs are increasingly being deployed in a large number of settings by minimally trained "first responders," such as police, firemen, security guards, and others.
- *Implantable Cardioverter Defibrillators (ICDs).* ICDs are being implanted in patients known to be at risk of sudden cardiac arrest to protect them from sudden cardiac death.
- *Antiarrhythmic Medication*.

VII. Marketing History

The WCD® 2000 device has obtained CE marking and approved for sale in the European Union (EU). However, there have been neither sales nor payments for these devices to date. The WCD® 2000 device has not been withdrawn from the market in any country for any reason related to safety and effectiveness.

VIII. Adverse Events

Patient Deaths

Within the enrolled population of 289 patients, 12 deaths were reported in the study (see Table 2 below). In only one case was the death judged to be device-related. The patient had a VT/VF event that was detected by the device. However, the front therapy electrode was incorrectly placed (reversed) by the patient. Because of this, the device detected an abnormally high electrical circuit impedance through the patient and did not deliver the shock. Subsequent to this event, the device has been modified so that the therapy electrodes can only be placed in the patient-worn chest garment the correct way.

Table 2. Description of Patient Deaths that Occurred in the Study (n=289 patients)

Description	Frequency of occurrence	Cardiac/Non-cardiac	Device related?
Incorrect placement of front therapy electrode.	1	Cardiac	Yes
Died while hospitalized and not wearing the device	4	Cardiac	No
Died while at home and not wearing the device	7*	Cardiac	No

*Two patients were no longer routinely wearing the device. One patient died while removing the device to shower. The cause of death in the other patient was determined to be a non-sudden cardiac event. One patient left the hospital against medical advice and died before resuming device use. The circumstances of the remaining two patient deaths are unknown.

Reported Adverse Events
The adverse events that occurred during the study are listed according to their frequency of occurrence (Table 3.). Adverse events are classified as either *Complications*, i.e. device related hospitalization, or *Observations*, i.e., requiring minimum intervention, no hospitalization.

Table 3. Adverse Events Tabulated by Frequency (n=289 patients)

	# of Patients with AEs	% of Patients with AEs	# of AEs	AE/Patient Years	Device related?
Complications Total	0	0	0	0	NA
Observations Total	32	11.4%	35	0.48	
Skin rashes	17	5.9%	20	0.27	Yes
Inappropriate defibrillation	6	2%	6	0.08	Yes
60 cycle interference	2	0.69%	2	0.03	Yes
Pacemaker interaction	1	0.3%	1	0.013	Yes
Loss of contact between battery and monitor	1	0.3%	1	0.013	Yes
Left jugular thrombosis	1	0.3%	1	0.013	No
No shock delivery	1	0.3%	1	0.013	Yes
Discomfort at front therapy pad	1	0.3%	1	0.013	Yes
Arrhythmia detection aborted	1	0.3%	1	0.013	Yes
Device disabled during arrhythmia detection	1	0.3%	1	0.013	Yes

Potential Adverse Events
Potential adverse events are listed in order of seriousness:

- Failure to sense and detect a treatable arrhythmia resulting in death.
- Unsuccessful cardioversion or defibrillation resulting in death or disability.
- Inappropriate shock causing abnormal heart rhythms, including fatal rhythms.
- Improper, ineffective, or non-operation of the device due to external causes such as electromagnetic interference.
- Failure resulting from random component failure.
- Ineffective cardioversion/defibrillation by another external defibrillator if the WCD® 2000 device is not removed from patient as advised by the chest belt label
- Fire hazard in the presence of a high oxygen concentration.
- Bystander shock from patient contact during a treatment event.
- Superficial skin burns resulting from defibrillation.
- Skin ulcers and allergic dermatitis due to constant and continual electrode/skin interactions.

IX. Summary of Pre-Clinical Studies

Prior to initiating the clinical studies, laboratory testing was conducted in accordance with established national and international industry standards (see Table 4, Summary of Non-clinical Testing). Where no applicable standards exist, testing was conducted per Lifecor, Inc. product specifications and test requirements. IEC stands for International Electrotechnical Commission and ISO stands for International Standards Organization. AAMI refers to a US national standard and stands for Association for the Advancement of Medical Instrumentation.

Biocompatibility testing, animal testing, and a simulated use study were also performed. In addition, a non-significant risk study was conducted on 200 patients undergoing electrophysiology testing from May 1987 to June 1995. Data collected from dual channel ECG recordings were used for detection algorithm development and test validation purposes. The algorithm was found to be 100 percent sensitive for VF and 95 percent sensitive for VT.

Biocompatibility Testing

Forty-three garments (worn) and numerous fabric samples underwent wear testing, cytotoxicity, and skin irritation tests in accordance with ISO 10993, Biocompatibility Testing of Medical Devices. The materials were established to be biocompatible.

Animal Study

Animal testing was performed using a porcine model (n = 2) to demonstrate successful defibrillation by the WCD® device and to evaluate the effect of an electrostatic discharge to the body while the device is worn. The skin under the therapy electrodes was examined and only erythema noted. Electrostatic discharges of up to 20 kV were applied to the animal's body while the device was charging and maintaining a charge with no effect on the device. The WCD® 2000 device successfully defibrillated five consecutive times.

Simulated Use Study

The WCD® Response Test was designed to quantify the false shock rate and the failure rate of response button use. During this test, 80 patients without heart disease wore a modified (no potential for shocking) device for a maximum of four days each, totaling 275 days of wear. Each patient received six to ten randomly timed alarms per day. Data generated from 2562 such alarm/responses showed 15 failures to respond, all occurring during sleep. The response failure rate was one in 170 alarms. It was also found that there was one true sustained false detection during 275 subject days. From this data it was predicted that the risk of false shock due to algorithm misinterpretation was approximately 1 in 128 years.

Table 4. Summary of Non-clinical Testing

Component Qualification Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
NiCad Battery characterization: 68 cycles of 24-hour charge/discharge cycles then delivery of 5 full energy pulses	48	Pass
High Voltage aluminum electrolytic capacitors: characterization and qualification specifically leakage current, capacitance, dielectric withstand voltage	100	Pass
38mg gas generator qualification to meet "no-fire" specification	35	Pass
Domed electrode characterization test: capacitance comparison	2 domed, 1 flat ECG electrode	Pass
Domed electrode thermal cycling test	10	Pass
Electrode belt cable qualification of mechanical and electrical properties	4	Pass
Endurance test of membrane switch (1 million cycles)	1	Pass

Electrical Safety Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Safety testing of the monitor, alarm module and expansion port in accordance with IEC 601-2-27, (Particular requirements for electrocardiographic monitoring equipment)	1	Pass
Safety testing of the monitor in accordance with IEC 601-1 (General requirements for safety medical electrical equipment) and IEC 601-2-4 (Particular Requirements for safety cardiac defibrillators)	1	Pass
Electrical isolation of the modem cable in accordance with IEC 601-1 (General requirements for safety medical electrical equipment)	1	Pass

Electrical Circuit Verification Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Monitor verification (testing of all functional parameters of hardware (analog and digital) and component interfaces)	3	Pass
Diagnostic Tester verification test of all design input requirements	1	Pass
Modem/computer cable verification test of all design input requirements	1	Pass
Defibrillator verification testing to verify accuracy of pulse delivery in accordance with ANSI/AAMI DF2.	1	Pass
DC-DC Converter verification testing of slow charge, overvoltage, time to charge and input voltages	1	Pass

Garment and Holster Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Chest garment verification of size, weight, assembly, washability requirements	1	Pass
Holster verification of size, weight, assembly, washability requirements	1	Pass

Electrode Belt Verification Tests

Test performed	*Sample size each test*	*Test results (Pass/fail)*
ECG signal transition board verification of resistance	1	Pass
Therapy electrode PCB assembly verification of current steering	1	Pass
Therapy electrode verification of thermal, dimensional, electrical and gel delivery requirements	1	Pass
Driven ground buffer verification of all electrical requirements	1	Pass

Reliability Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Delivery of 2500 max energy pulses	1	Pass
Garment and holster field performance	359 garments, 67 holsters	Pass
Therapy electrode gel delivery at end of life reliability	459	Pass
Temperature accelerated life test of the WCD® 2000 system	3	Pass

Electromagnetic Compatibility Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Verification of device performance for radiated and conducted emissions and ESD in accordance with EN 60601-1-2, Electromagnetic compatibility – Requirements and tests, which includes the following test methods and procedures: • EN 55011:1998 Radiated and Conducted Emissions – Group 1, Class A performed in accordance with CISPR 11 Limits and methods of measurement of radio disturbance characteristics of industrial, scientific, and medical (ISM) radio-frequency equipment. • EN 61000-4-2:1995 Electrostatic Discharge Immunity Test – Performance Criteria A. • IEC 801-3:1984 Radiated RF, EM Field Immunity Test – Performance Criteria A. • EN 61000-4-3:1997 Radiated RF, EM Field Immunity Test – Amplitude Modulated – Performance Criteria A. • EN 61000-4-8:1993 Power Frequency Magnetic Field Immunity Test – Performance Criteria A.	1	Pass
Verification of device performance when exposed to typical high frequency and electromagnetic electronic devices that may be encountered by patients in every day life These devices included hand-held cellular telephones, vehicle-mounted cellular telephones, airport security detection devices, and electronic article surveillance (EAS) systems.	1	Pass

Environmental Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Verification of device performance over ranges of temperature, altitude and humidity	1	Pass

Mechanical Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Monitor enclosure verification of mechanical strength and impact in accordance with IEC 601-1 subclauses 21a, 21b, and 21.5, and spillage and dielectric strength requirements in accordance with IEC 601-2-4 subclause 44.3.	1	Pass
Alarm module enclosure verification of strength and impact in accordance with IEC 601-1 subclauses 21a, 21b, and 21.5, and liquid ingress requirements in accordance with IEC 601-2-4 subclause 44.3.	1	Pass

Software Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Verification of the functionality and performance of all WCD® 2000 device application software	1	Pass (DSP System software version is 93L0162-V02.4, HC11 System software version is 93L0104-V02.3)

System Validation Testing

Test performed	*Sample size each test*	*Test results (Pass/fail)*
Validation of proper alarms, notification sequences, commands and event flags	1	Pass
Trans-telephonic transmission verification	1	Pass
Simulated use of overall system	10	Pass
Simulated use test for proper function and ease of use	3	Pass
Detection algorithm validation using proprietary LIFECOR developed ECG rhythm database	2	Pass
WCDNET functionality and performance	1	Pass
Suitability and performance of packaging and shipping	1 of each component	Pass

XI. Clinical Studies

1. Electrophysiology Laboratory Feasibility Study - October 1996 to September 1997

Ten patients were electively induced into VT or VF, and all ten were converted or defibrillated with the first 230 Joule WCD® 2000 device delivered shock. There were no post-shock arrhythmias or skin burns. The average time from induction to treatment was 28 +/- 15 seconds. The average patient impedance was 54 +/- 13 ohms.

2. In-Hospital Feasibility Study - April 1997 to January 1998

The objective of the study was to evaluate the risk of an unnecessary shock and to obtain, if possible, documentation of a full automatic detection and defibrillation of spontaneous VT/VF events. Fifteen patients wore the WCD® 2000 device in the hospital for a total of 58 days with no automatic treatments or unnecessary shocks.

3. Pivotal Clinical Trial – February 1998 to July 2001

Objective. The objective of the study was to demonstrate safety and effectiveness of the WCD® 2000 device. The safety objective was to demonstrate less than 2.3% false shocks per patient-month with 90 percent confidence. A minimum of 500 patient months of weartime experience was required. The effectiveness objective was to demonstrate greater than 25% resuscitation success with 90 percent confidence.

Method. A prospective, non-randomized, multi-national trial involving 16 centers (15 U.S. centers and 1 European center) evaluated the safety and effectiveness of the WCD® 2000 device with patients at risk of sudden cardiac death. Historical controls of Emergency Medical Services, sudden cardiac arrest (SCA) survivorship, and reported ICD unnecessary shock frequency were used to establish comparative success criterion for WCD® 2000 device safety and effectiveness. Two populations at SCA risk were chosen for the investigation. The first population (WEARIT) consisted of patients waiting for heart transplant or patients having an equivalent cardiac status, namely New York Heart Association Class III or IV heart failure and an ejection fraction below 30 percent. Typically, these patients used the WCD® 2000 device until they received a heart transplant, a circulatory assist device, or an ICD. The second patient population (BIROAD) included acute myocardial infarction (MI) patients and patients immediately following a coronary artery bypass graft procedure. Additional requirements for both the MI and bypass patients included VT/VF within the first 48 hours or a left ventricular ejection fraction of less than 30 percent. A Killip Class III or IV 72 hours following the MI and syncopal VT/VF after 48 hours post-MI also qualified patients for WCD® 2000 device use. The post-MI patients used the WCD® 2000 device for approximately four months. Patient characteristics are summarized in Table 5.

Table 5. Patient Demographics

	Total Study	BIROAD (n=177)	WEARIT (n=112)
Ejection fraction	23% ±10, n=282	30% ±10, n=107	19% ±7, n=175
QRS width (msecs)	121±33, n=261	109±20, n=109	128±38, n=152
Age (years)	55±12, n=288	59±11, n=111	52±11, n=177
Male	82%, n=237	83%, n=93	81%, n=143
History of smoking	66%, n=288	67%, n=112	65%, n=176
History of hypertension	59%, n=288	81%, 112	44%, n=176
History of nonsustained ventricular tachycardia	52%, n=267	71%, n=105	40%, n=162
History of sustained ventricular tachycardia	32%, n=259	51%, n=102	20%, n=157
Beta-blocker medications	57%, n=285	70%, n=111	49%, n=174
Anti-arrhythmia drugs	22%, n=285	18%, n=111	25%, n=174
Inotropic medications	16%, n=285	3%, n=111	25%, n=174

Study Results. The study population consisted of 289 patients with 873 patient months (72.7 years) of patient device experience, an exposure mean of 94 days (ranging from 1-1032 days) for individual patient exposures, and an average daily wear time of 19.1 +/- 5.7 hours (Table 6). The device successfully treated five of seven correctly diagnosed spontaneous events of sudden cardiac arrest (Table 7).

Table 6. Average daily device wear time

	Total Study (n=289)	BIROAD (n=112)	WEARIT (n=177)
Average use (hours/day)	19.1±5.7	20.1±6.3	18.7±5.3

Table 7. Summary of Study Results (n=289 patients)

Event Description	Number or Events
SCA events with device being worn	**7**
SCA events correctly diagnosed	**7**
SCA events successfully treated*	**5**
Unnecessary shock episodes**	**6**

*Two out of 7 events were not treated because the patient incorrectly assembled the therapy electrodes in the chest garment. Changes were subsequently implemented to prevent these human failures from re-occurring.

** No deaths, arrhythmia inductions, or injury resulted from these unnecessary shocks. Using the ECG recordings that documented the unnecessary shocks, algorithm software changes were implemented to reduce the future probability of unnecessary shocks.

Safety results
The most frequent adverse event reported was a temporary skin rash. There were six unnecessary shock episodes during 873 months of accumulated patient use. The unnecessary shock rate per patient-month was 0.69% with 90 percent confidence interval (0.30, 1.35). No arrhythmias were induced from the unnecessary shocks. Two failures must occur for an unnecessary shock to happen. First, the detection algorithm must falsely declare an arrhythmia to exist for the duration of the alarm sequence (at least 25 seconds). Second, the patient must fail to use the response buttons despite the alarms.

Modifications were made to the WCD® 2000 device after carefully reviewing the circumstances during which the unnecessary shocks occurred. The modifications included changes to the design in the noise and arrhythmia alarms as well as, modifications to the detection algorithm. These changes were implemented during the last year of the study. During that time, no false shock episodes occurred.

Effectiveness results
The device successfully detected and treated 5 sudden cardiac arrest episodes. The device detected but was unable to treat two other sudden cardiac arrest episodes resulting in a 71 percent successful resuscitation rate.

The hypothesis for the effectiveness objective was that the successful resuscitation rate using the WCD® 2000 device would be at least 25% (see Method Section above). A confidence level of 90% was chosen for the minimum boundary of acceptance or rejection. An additional requirement of the study design was that the power must be at least 50% if the true successful resuscitation rate was 43%. The true successful resuscitation rate was estimated to be between 43% and 90% based on a ventricular detection success rate of 85% to 95 % and a defibrillation success rate of 50% to 95%. From these requirements, the trial was designed as a sequential evaluation of SCA events occurring while the device was worn. The results were evaluated by stopping rules to determine if the hypothesis could be accepted or rejected. The stopping rules were (s is a successful resuscitation event, f is an unsuccessful resuscitation event):

- Stop with a favorable conclusion whenever $s \geq 4 + f/3$
- Stop with an unfavorable conclusion whenever $f \geq 7 + s/7$.

This design met the power requirement of at least 50% if the true WCD® 2000 device successful resuscitation rate was only 43% and would have a power over 90% for true rates over 60%. A graph of the resuscitation successes versus failures is shown in Figure 2 below.

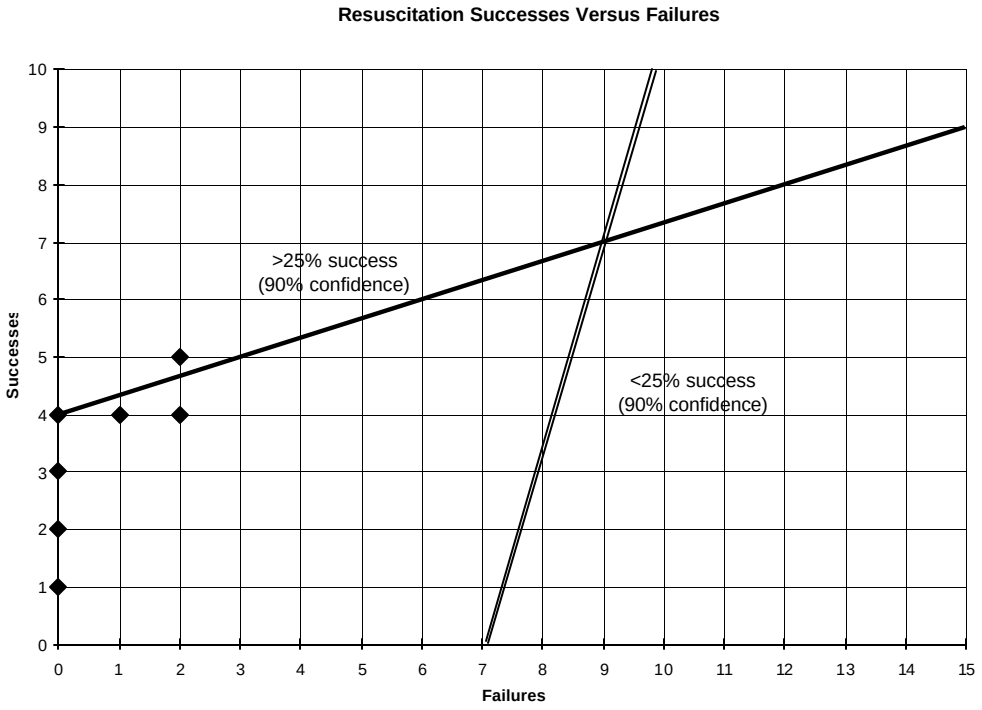

Figure 2.

XI. Gender Analysis

Of all patients enrolled (n = 289), 18% were female. This is consistent with the typical gender distribution of patients on cardiac transplant waiting lists and in the immediate post-myocardial infarction, the intended populations for device use. A review of the subjects who are no longer wearing the device was made and no additional bias was identified. The results, shown below (Table 8), may vary from the numbers given for the overall study because it contains only those who have left the study.

Table 8. Gender Distribution and Characteristics (n=289)

	Male	**Female**
Months of use	608 (79%)	158 (21%)
Age	51.3 years	55.6 years
Ejection fraction	23.9%	22.8%
QRS width	120 msec.	121 msec.

The safety and effectiveness data were separated by sex for examination (Table 9). When considering the ratio of females and males enrolled in the study, the ratio of false shock episodes was approximately the same. The number of treatable events while wearing the device was about the same for males and females as was the number of successfully treated events. Thus, both safety and effectiveness appear similar in men and women.

Table 9. Gender Comparison of Safety and Effectiveness Data (n=289)

	Total	Male	Female
False shock episodes	6 (100%)	5 (88%)	1 (12%)
Treatable events	7 (100%)	3 (43%)	4 (57%)
Successful treatments	5 (100%)	2 (40%)	3 (60%)
% Successful	71%	67%	75%

XII. Conclusions Drawn from the Studies

All of the relevant non-clinical laboratory testing (including biocompatibility testing, animal study, and simulated use testing) was conducted prior to the clinical studies of the WCD® 2000 device. Further, based on a trial design that used sequential evaluation of resuscitation events, the clinical study demonstrated a successful rate of at least 25% with 90% statistical confidence. Thus, the results of the bench tests, animal and clinical studies provide reasonable assurance of safety and effectiveness of the WCD® 2000 System, including all of the associated components, when used as indicated in accordance with the directions for use.

XIII. 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 risks to health in external defibrillation are clearly characterized and well known by the medical community and by this panel. There are no new clinical issues related to safety and effectiveness.

XIV. 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 Lifecor, Inc.'s manufacturing facility to be in compliance with the Device Quality System Regulation (21 CFR part 820).

XV. 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.