SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name:	Permanent drug-eluting pacemaker electrode
Device Trade Name:	ACUITY™ Steerable Lead Models 4554, 4555, and 4556
Applicant's Name and Address:	Guidant Corporation 4100 Hamline Avenue North St. Paul, MN 55112-5798
Date of Panel Recommendation:	None
Pre-Market Application (PMA) Number:	P050046
Date of Notice of Approval to Applicant:	April 13, 2007

II. INDICATIONS FOR USE

The Guidant ACUITY™ Steerable IS-1 coronary venous, steroid-eluting, dual electrode pace/sense leads are transvenous leads intended for chronic, left-ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator. Extended bipolar pacing and sensing is available using ACUITY™ Steerable with an RV pace/sense/defibrillation lead or a bipolar RV pace/sense lead.

III. CONTRAINDICATIONS

Use of the ACUITY lead is contraindicated in patients with:

- patients with a hypersensitivity to a nominal dose of 1.0 mg (0.5 mg per electrode) of dexamethasone acetate drug
- mechanical tricuspid heart valves
- obstructed or inadequate vasculature for intravenous catheterization.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the ACUITY™ Steerable lead labeling.

V. DEVICE DESCRIPTION

The Guidant ACUITY™ Steerable lead is a device/drug combination product made up of two regulated components: a device (the left ventricular ACUITY Steerable lead) device and a drug component (dexamethasone acetate). The characteristics for the lead appear in **Table 1**.

Table 1: Design of ACUITY Steerable Lead

Characteristic	ACUITY Steerable Lead
Model number and Length	Model 4554, 80cm Model 4555, 90 cm Model 4556, 100 cm
Terminal Compatibility	IS-1, Bipolar
Terminal Pin / Ring Material	Titanium or Titanium Alloy
Terminal Seal Material	Silicone Rubber
Pulse Generator Compatibility	Guidant Pulse Generators that accept IS-1 Connectors
Serial Number Label	Laser-marked titanium dioxide polyurethane tubing
Lead Body Diameter	Polyurethane - 1.98mm (6F) Silicone - 1.88mm (5.7F)
Conductor Coils	Coaxial coil design with distal two-dimensional J shaped bias. Inner conductor: Quad-filar MP-tantalum core wire heat-treated at 275°F. Outer Conductor: Trifilar platinum-clad tantalum wire coated with ETFE fluoropolymer.

Characteristic	ACUITY Steerable Lead
Electrical Insulation	Silicone tubing provides primary insulation between coaxial conductors and on the distal portion of the lead body. Polyurethane provides primary insulation on the proximal lead body. ETFE coating on the outer coil filars provides an additional barrier.
ETFE Filar Coating	Outer conductor coil filars are individually coated. Coating terminates just proximal to the proximal electrode.
Lead Body Inner Insulation Material	Sil-glide coated silicone tubing provides primary insulation between coaxial conductors and on the distal portion of the lead body is 75A durometer.
Lead Body Outer Insulation Material (Polyurethane Lead Body)	55D Polyurethane provides primary insulation from the environment on the proximal lead body (from terminal connector to approximately 2 cm proximal to tip of lead).
Lead Body Outer Insulation Material (Distal Silicone Lead Section)	Sil-glide coated silicone tubing (55A durometer) provides primary insulation from the environment on the distal lead body (from Polyurethane Lead Body Tubing to the proximal electrode). A silicone rubber molded section (50A durometer) provides primary insulation from the environment on the distal lead body (from Proximal Electrode to the distal tip electrode).
Distal Silicone Section Length	2.0 cm
Atraumatic Tip	Rounded Tip electrode with silicone rubber neck between electrodes. OD of 0.074" tapers to 0.070".
Proximal Electrode	IROX coated platinum/iridium, 2 part (inner and outer) full circumference design; Outer ring OD 0.074" Length 0.060" Calculated exposed surface area is 9.0mm^2.
Distal Electrode	IROX coated platinum/iridium, tip electrode design. Tip OD 0.070" Tip Length 0.050" with a hemi-spherical end Calculated exposed surface area is 7.8 mm^2.
Stylet Stop	Stylet stop prevents it from exiting the distal tip

Characteristic	ACUITY Steerable Lead
End Ring	Not Applicable
Electrode Spacing	8 mm longitudinal spacing between proximal and distal electrodes.
Fixation	Distal lead body J-shape: J-Radius 11.4 mm (centerline) Length 40 mm
Steroid Eluting Collar	Two Dexamethasone acetate (DXA) and silicone rubber collars; one distal to the proximal electrode and one proximal to the distal electrode. ID 0.058", OD 0.070" Length 0.060". Nominal Dose 0.050 mg per collar
Suture Sleeve	A triple grooved, silicone rubber, TiO_2 pigmented, suture sleeve is assembled onto the lead body.

A. Device Component Description

Guidant ACUITY™ Steerable coronary venous pace/sense leads, Models 4554/4555/4556, provide chronic left ventricular bipolar pacing and sensing. Lead diameter is 6 Fr. The leads have an over-the-wire design with an IS-1 bipolar connector and are steroid-eluting at the proximal and tip electrodes. The lead is anchored with J-shaped fixation and the electrodes are IROX coated (iridium oxide). Placement is achieved by inserting the lead through the coronary sinus and placing it into a branch of the cardiac veins using a stylet or an over-the-wire delivery accessory. The stylet or guide wire can be retracted or advanced within the "J"-shape to deflect the tip and steer the lead into coronary venous branch veins. A step in the tip electrode lumen allows engagement of the stylet tip and stops it from exiting the distal tip of the lead. The tip of the lead is design to allow a guidewire to pass through for over-the-wire delivery. The ACUITY Steerable lead is used in conjunction with a compatible pulse generator.

The lead and accessories are supplied sterile. Each package contains one lead (with an anchoring sleeve already attached, a stylet/guidewire guide in-place), two stylets, and a vein lifter.

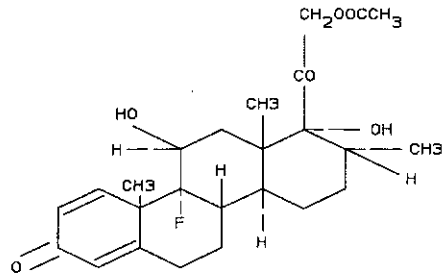
B. Drug Component Description

The active drug component in the ACUITY Steerable lead is dexamethasone acetate (DMA). This is an anti-inflammatory steroid that is a white crystalline solid with a melting point of 238-240°C and maximum UV of 239 nm (Merck Index, Twelfth edition 1996). The structural formula is shown in **Figure 1**.

The target dose of DMA on the steroid collar is 0.5 mg. The ACUITY Steerable lead contains two (2) drug components (steroid collars).

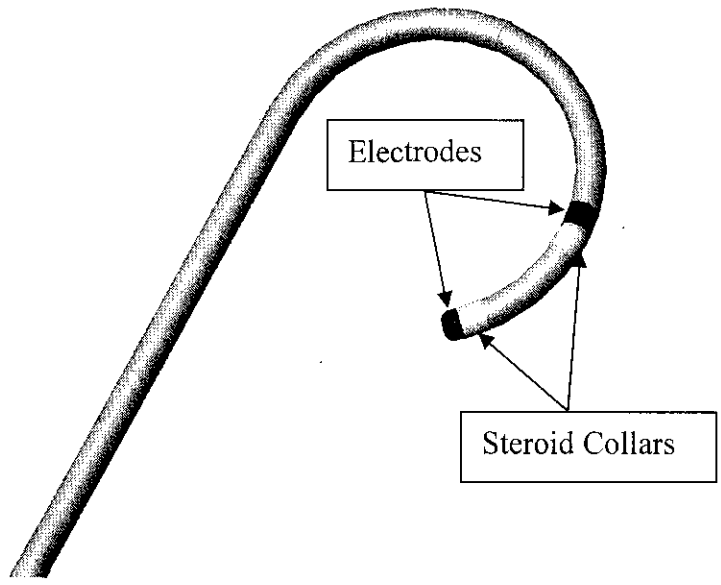
Each collar consists of DMA in a silicone rubber matrix, which is positioned adjacent and distal to each electrode. **Figure 2** depicts the drug component on the lead.

Figure 1: Structural Formula of Dexamethasone Acetate



$C_{24}H_{31}FO_6$ mw=434.50

Figure 2: Location of Drug Component (Steroid Collar)



C. Dexamethasone Mechanism of Action

Steroids suppress the inflammatory response that is believed to cause threshold rises typically associated with implanted leads. Dexamethasone is a synthetic steroid of the glucocorticoid family. Glucocorticoid steroids have potent anti-inflammatory actions via direct and indirect effects on major inflammatory cells. While the mechanism of action of glucocorticoids is not fully understood, it is known that glucocorticosteroids bind to a cytoplasmic glucocorticoid receptor as well as to a membrane-bound receptor. Binding to the cytoplasmic receptor, the receptor becomes activated and leads to translocation to the nucleus. The receptor interacts with specific DNA sequences (glucocorticoid responsive elements) within the regulatory regions of affected genes. Thus, glucocorticoids inhibit the production by multiple cells of factors that are critical in generating the inflammatory response, in particular via modulation of transcription factors.

VI. ALTERNATIVE PRACTICES OR PROCEDURES

The present established therapies include the use of commercially available left ventricular leads.

VII. MARKETING HISTORY

The ACUITY Steerable lead is currently distributed commercially outside the United States. Specifically, this lead is approved for sale in the European Union.

The ACUITY Steerable lead has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VIII. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

A. Potential Adverse Events

Based on the literature and lead implant experience, the following alphabetical list includes possible adverse events associated with implantation of an implantable cardioverter defibrillator and/or pacemaker lead system:

- Acceleration of arrhythmias
- Adverse reaction to procedure (e.g., bradycardia, general, respiratory, hypotension)
- Air embolism
- Allergic reaction
- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Conductor coil fracture
- Coronary venous spasm
- Death
- Elevated thresholds
- Erosion/extrusion
- Extracardiac stimulation (e.g., phrenic, diaphragm, chest wall)
- Fibrotic tissue formation (e.g., keloid formation)
- Fluid accumulation
- Formation of hematomas or cysts
- Heart block
- Inappropriate therapy (e.g., shocks, ATP, pacing)
- Incomplete lead connection with pulse generator
- Infection
- Lead displacement/dislodgement
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- Local tissue reaction
- Muscle and nerve stimulation

- Myocardial trauma (e.g., cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-medicated tachycardia
- Pericardial rub, effusion
- Pneumothorax/hemothorax
- Random component failures
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thrombosis/thromboemboli
- Valve damage
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)

In addition to the implantation of an implantable cardioverter defibrillator and/or pacemaker lead system, possible adverse events associated with implantation of a coronary venous lead system are listed below in alphabetical order:

- Allergic reaction to contract media
- Breakage/failure of implant tools
- Coronary venous occlusion
- Coronary venous trauma (e.g., perforation, dissection, erosion)
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contract media used to visualize coronary veins

B. Observed Adverse Events (AE)

The safety of the ACUITY Steerable lead was evaluated in 110 patients who underwent an implant procedure for the ACUITY Steerable lead in the ACUITY Steerable clinical study conducted in the United States. Safety and effectiveness endpoints were based on three-month follow-up data.

Investigators were required to report adverse events during the clinical study according to the definitions in the protocol. Investigators were required to provide a detailed description of the AE, with suspected cause, including information on the relation of the AE to the device, procedure or investigation, what corrective actions were taken and what the clinical outcome was for the patient.

ACUITY Steerable lead-related adverse events were defined as all lead-related or procedure-related adverse events attributed to the ACUITY Steerable lead by the investigator, or when the ACUITY Steerable lead could not be ruled out as the course of the adverse

event. Those adverse events attributed to commercially available guide wires, guide catheters and diagnostic electrophysiology catheters were excluded from the ACUITY Steerable lead-related adverse events, and were categorized as procedure-related adverse events.

All adverse events were further classified as an observation or complication based on the following definitions:

- Observation: A clinical observation is a clinical event that does not result in invasive intervention, injury, or death, and is not an unanticipated adverse event. Corrective actions are simple adjustments such as reprogramming of the pulse generator or oral antibiotic treatment of a pocket infection.

- Complication: A clinical complication is a clinical event that results in invasive intervention after implant, injury, or death (e.g., surgical evacuation of a hematoma, lead dislodgment requiring lead repositioning, generator replacement, intravenous antibiotic treatment of a pocket infection). A complication is an event that results in an outcome classified as serious, unanticipated, or death.

Table 2 provides information on adverse events (AEs) reported from implant through the three-month follow-up visit. In the 110 patients attempted or implanted with the ACUITY Steerable lead, there were 30 lead-related events (27 patients), including 10 that were classified as complications and 20 that were classified as observations.

Table 10 summarizes all AEs reported in the study, including those that occurred beyond the three-month follow-up. Thus, it includes data beyond the 3-month endpoint time frame. This all inclusive list of AEs is located in **Appendix A** of this document.

Table 2: Clinical Observation and Complications Summary

All patients implanted or attempted; N=110
Total device months = 313
Includes all adverse events reported through three months of follow-up

		Complications		Observations	
Adverse Event	**Number Of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Total Adverse Events	**103 (61)**	**27.3 (30)**	**11.8 (37)**	**40.0 (44)**	**21.1 (66)**
ACUITY Steerable Related Events (N=101)					
Coronary venous dissection	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.3 (1)
Dislodgment - Elevated threshold - LV	2 (2)	2.0 (2)	0.7 (2)	0.0 (0)	0.0 (0)
Dislodgment - Extracardiac stimulation - LV	4 (4)	2.0 (2)	0.7 (2)	2.0 (2)	0.7 (2)
Dislodgment - Multiple signs - LV	2 (2)	2.0 (2)	0.7 (2)	0.0 (0)	0.0 (0)
Dislodgment - No reported signs - LV	1 (1)	1.0 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Dislodgment - Unable to capture - LV	2 (2)	2.0 (2)	0.7 (2)	0.0 (0)	0.0 (0)
Elevated threshold - LV	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.7 (2)
Extracardiac stimulation - LV	16 (15)	1.0 (1)	0.3 (1)	13.9 (14)	5.1 (15)
Subtotal ACUITY Steerable Related Events	**30 (27)**	**8.9 (9)**	**3.4 (10)**	**18.8 (19)**	**6.8 (20)**
PG Related Events (N=106)					
Elevated DFT - Defibrillation	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Extracardiac stimulation - Daily impedance testing	2 (2)	0.0 (0)	0.0 (0)	1.9 (2)	0.6 (2)
Hematoma - Pocket (> 30 days post-implant)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Migration	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Pacemaker-mediated tachycardia (PMT)	2 (2)	0.0 (0)	0.0 (0)	1.9 (2)	0.6 (2)
Psychological effect due to device therapy	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Subtotal PG Related Events	**8 (7)**	**0.0 (0)**	**0.0 (0)**	**6.6 (7)**	**2.6 (8)**
RA Lead Related Events (N=106)					
Dislodgment - Unable to capture - RA	2 (2)	1.9 (2)	0.6 (2)	0.0 (0)	0.0 (0)
Elevated threshold - RA	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Oversensing - RA	2 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.6 (2)
Unable to capture - RA	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)

		Complications		Observations	
Adverse Event	Number Of Events (Number of Patients)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Subtotal RA Lead Related Events	**6 (4)**	**2.8 (3)**	**1.0 (3)**	**0.9 (1)**	**1.0 (3)**
RV Lead Related Events (N=106)					
Dislodgment - Elevated threshold - RV	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Elevated threshold - RV	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Subtotal RV Lead Related Events	**2 (2)**	**1.9 (2)**	**0.6 (2)**	**0.0 (0)**	**0.0 (0)**
Procedure Related Events (N=110)					
Adverse reaction - Hypotension	2 (2)	0.9 (1)	0.3 (1)	0.9 (1)	0.3 (1)
Chest pain	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Hematoma - Pocket (<=30 days post-implant)	6 (6)	0.9 (1)	0.3 (1)	4.5 (5)	1.6 (5)
LV Lead Insulation Damaged During Procedure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Post-surgical wound discomfort	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Psychological effect due to recall	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.6 (2)
Thrombus	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Subtotal Procedure Related Events	**14 (12)**	**3.6 (4)**	**1.3 (4)**	**8.2 (9)**	**3.2 (10)**
Protocol Testing Related Events (N=110)					
Extracardiac stimulation - LV	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.6 (2)
Subtotal Protocol Testing Related Events	**2 (2)**	**0.0 (0)**	**0.0 (0)**	**1.8 (2)**	**0.6 (2)**
Cardiovascular Related Events (N=110)					
Atrial fibrillation (AF)	4 (3)	0.9 (1)	0.3 (1)	1.8 (2)	1.0 (3)
Cerebrovascular accident (CVA)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Chest pain - Heart failure	2 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.6 (2)
Chest pain - Ischemic	2 (2)	0.9 (1)	0.3 (1)	0.9 (1)	0.3 (1)
Chest pain - Other	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Chronotropic incompetence	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Dizziness	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Dizziness - Heart failure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Dyspnea - Heart failure	2 (2)	1.8 (2)	0.6 (2)	0.0 (0)	0.0 (0)
Hypotension - Heart failure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Multi-system failure - Heart failure	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Multiple heart failure symptoms	9 (8)	5.5 (6)	1.9 (6)	2.7 (3)	1.0 (3)
Multiple symptoms	2 (2)	0.9 (1)	0.3 (1)	0.9 (1)	0.3 (1)

		Complications		Observations	
Adverse Event	Number Of Events (Number of Patients)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Myocardial infarction	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Other SVT (AVRT, AVNRT, EAT etc.)	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.6 (2)
Sinus tachycardia	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Ventricular fibrillation (VF)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Subtotal Cardiovascular Related Events	**33 (26)**	**10.9 (12)**	**4.2 (13)**	**13.6 (15)**	**6.4 (20)**
Subtotal Non-cardiovascular Related Events	**8 (7)**	**3.6 (4)**	**1.6 (5)**	**2.7 (3)**	**1.0 (3)**

As of March 21, 2006, a total of 4 deaths out of 106 implants were reported in the study. Of these deaths, 2 have been adjudicated by the Morbidity and Mortality Events Committee as Cardiac: Unknown and the second as Cardiac: Pump Failure. The deaths not yet adjudicated were reported by the principal investigator as Cardiac: Unknown and Cardiac: Pump Failure. None of these deaths have been attributed to the investigation or the ACUITY Steerable lead.

IX. SUMMARY OF PRE-CLINICAL STUDIES

A. Biocompatibility Studies

The materials used in the ACUITY Steerable leads that are directly exposed to body tissues or fluids are summarized in **Table 3**. Most of the materials are identical to the materials used on previous Guidant lead designs. Biocompatibility assessment was previously performed in accordance with ISO 10993-1, Biological Evaluation of Medical Devices: Evaluation and Testing. All materials were found to be biocompatible.

Table 3: Biocompatibility Information

Material (polymer/metal/ ceramic/composite	Component Name Subject Device	Component Predicate Device	Predicate Device Name	Approval Date
Tecothane TT 1075D-M	Molded Terminal Assembly	Molded Terminal Assembly	EASYTRAK 3 LV-1,	P010012/S025 06AUG-04
Titanium- ASTM grade 5	Terminal Pin	Terminal Pin	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Titanium- ASTM grade 5	Terminal Ring	Terminal Ring	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Titanium- ASTM grade 5	Terminal Outer Ring	Terminal Outer Ring	EASYTRAK 2 IS-1	P010012/S024 06AUG-04
Pellethane 2363-55D	Serial Number Label	Serial Number Label	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
TiO2 Pigment				
Pellethane 2363-55D	Serialized Heat Bonded PU Tubing Subassembly	Serialized Heat Bonded PU Tubing Subassembly	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
TiO2 Pigmented Tubing				
Liquid Silicone Rubber, DOW 7-6860	Front Seal	Front Seal	EASYTRAK 2 IS-1	P010012/S024 06AUG-04
Liquid Silicone Rubber, DOW 7-6860	Rear Seal	Rear Seal	EASYTRAK 2 IS-1	P010012/S024 06AUG-04
Platinum Clad Tantalum	Outer Coil Conductor Wire, ETFE coated	Outer Coil Conductor Wire, ETFE coated	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Ethylene tetrafluoroethylene (ETFE)				
MP/35N with Tantalum	Inner Coil	Inner Coil	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Silglide Coating	Outer Silicone Tubing	Outer Silicone Tubing	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Silicone Rubber, Nusil MED-4755				
Silglide Coating	Inner Silicone Tubing	Inner Silicone Tubing	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Silicone Rubber, Nusil MED5-4770**				
Platinum/Iridium (90/10)	Inner Proximal Electrode	Inner Proximal Electrode	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
IROX	IROX coated Proximal Ring	IROX coated Proximal Ring	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Platinum/Iridium (90/10)				
Platinum/Iridium (90/10)	Tip Electrode Crimp Tube	Tip Electrode Crimp Tube	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
IROX	IROX coated Tip Electrode	IROX coated Tip Electrode	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Platinum/Iridium (90/10)				
Liquid Silicone Rubber, DOW 7-6860	Silicone Molded Neck	Silicone Molded Neck	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Silicone Adhesive, Nusil MED-1514	Medical Adhesive	Medical Adhesive	EASYTRAK 2 IS-1	P010012/S024 06AUG-04
Polyurethane Adhesive, Polycin 937/Vorite 689	Polyurethane Adhesive	Polyurethane Adhesive	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Dexamethasone Acetate	Steroid Collar	Steroid Collar	EASYTRAK 3 LV-1	P010012/S025 06AUG-04
Liquid Silicone Rubber, DOW 7-6860				
Dow Corning 1200 Primer Coat, Clear	Silicone Primer	Silicone Primer	RELIANCE G/SG	P910073/S041 04NOV03 P910073/S035 02NOV00
TiO2 Pigment	Lead Stabilizer	Lead Stabilizer	EASYTRAK 2 LV-1	P010012/S024 06AUG-04
Platinum Cure Silicone Rubber, Dow Q7-4765				
White Silicone Paste, Ferro Corp 61-18000 and 61-18200				

** Nusil MED5-4770 is a new durometer of the same silicone rubber family. Biocompatibility testing was performed on the Nusil MED-4755 material

B. Engineering Testing

The ACUITY Steerable lead was tested to examine the electrical and mechanical integrity. Testing is summarized in **Table 4**.

Table 4: Engineering Testing

Summary of ACUITY Steerable Design Verification Testing	Sample Size	Test Results (Pass/Fail)
MDVT (Package, Mechanical, Electrical, and Suture Sleeve Lead Testing)		
Shipping Conditioning Subject the leads to simulated shipping conditions per ASTM D 4169-04 and ensure the lead meets visual criteria (ex. Ensure "J-shape" of lead is maintained) and withstands packaging stylet insertion/withdrawal forces	10	Pass
Packaging Visual Verify packaging literature, items properly positioned	10	Pass
Lead Visual – Insulation Structural Continuity Inspection: Verify the lead's insulation structure continuity meet specification. All pre-molded silicone elastomer sections and all components bonded with Medical Adhesive shall not exhibit delaminating or joint separation	20	Pass
Lead Visual – Device Length verification: Verify the lead's length.	20	Pass
Lead Visual – Device Diameter verification: Verify the lead's diameter	20	Pass
Lead Visual – Electrode Spacing: Verify electrode spacing.	20	Pass
Resistance: Verify direct current resistance. For 100 cm lead, max is 82Ω.	20	Pass
Insulation Integrity (Dielectric): Verify the integrity of the lead insulation between the conductor for the proximal electrode and the conductor for the distal electrode per the requirements of the Device Spec of less than 0.6 mA.	20	Pass
Insulation Integrity (Pressure): Verify the integrity of the insulation and bonds; they must display a leak rate between 0.030 and 0.165 cc/min once pressurized.	20	Pass
Packaging Stylet Insertion/Withdrawal: Verify the withdrawal force does not exceed a maximum of 0.25 Lb.	10	Pass
System Compatibility: Verify the lead is compatible with components (RAPIDO system and Finishing wires).	10	Pass
Fixation Stability: Verify the fixation method meets minimum allowable peak extraction force of 2.7g.	10	Pass
Pacing Impedance: Measure and record the pacing impedance. There is no acceptance criterion. Results showed pacing impedances ranged from 1199 to 1395 ohms.	10	N/A
Sensing Impedance: Measure and record the sensing impedance. There is no acceptance criterion. Results showed sensing impedances ranged from 10.5 to 10.6 K-ohms.	10	N/A
Axial Load: Meet CEN/CENELEC EN 45502-2-1, which includes max permanent elongation 5%, leakage current ≤2mA, and resistance test (see above)	10	Pass

Summary of ACUITY Steerable Design Verification Testing	Sample Size	Test Results (Pass/Fail)
Suture Sleeve Stability on Lead Body: Without being tied to lead, suture sleeve must not slide down lead.	10	Pass
Suture Sleeve Retention: Verify when tied to lead (with 3Lb force), it does not move more than 1 cm with a 0.5Lb load on lead.	10	Pass
Terminal Assembly Strength: Verify durability of terminal connector when subjected to torsional, compressive, and tensile forces. Lead must meet electrical performance criteria in Resistance and Dielectric testing (see above)	10	Pass
Corrosion		
Corrosion DVT: Verify inner coil is not functionally impacted by corrosion after 10-year pacing simulation. Leads must meet electrical & axial pull test.	8	Pass
Corrosion Assessment: Evaluate each component and metal-to-metal joint according to (1) environment the component will be exposed to, (2) determine possible corrosion modes, and (3) evaluate corrosion risk based on prior tests or well documented scientific justification when available. ACUITY Steerable has eight (8) metal components and six (6) metal-to-metal joints.	n/a – no testing was required per the evalua-tion	Pass
Packaging and Label Integrity		
Packaging: Verify the printed markings on the labels for lead and accessories meet applicable sections of EN 980:2003, EN 1041:1998, and EN 45502-1:1997	4	Pass
Particulate		
Particulate: Verify lead meets EN 45502 part 2-1	6	Pass
Flex Fatigue and (Bell Mouth)		
IS-1 Connector Flex Fatigue: Comply with EN 45502 Part 2-1 section 23.5	6	Pass
Bell Mouth Flex Fatigue Test of Polyurethane (PU) lead body: Comply with EN 45502-2-1 at 85,000 cycles.	8	Pass
Intracardiac Buckle Flex Fatigue in PU body: This test has been created unique to Guidant. After flexing in the polyurethane lead body, verify lead body conductor withstands ten years (420 million cycles) of flexing. Test is based upon minimum in-vivo intracardiac bend radius conditions. Sample must meet DC resistance of 166Ω for a 100 cm lead, 350Ω maximum change in DC resistance, and maintain ability to properly pace and sense.	8	Pass
Intracardiac Buckle Flex Fatigue in PU to Silicone transition and J-Shape: This test has been created unique to Guidant. After flexing in the distal tubing and bias zone, verify lead body conductor withstands ten years (420 million cycles) of flexing. Test is based upon minimum in-vivo intracardiac bend radius conditions. Sample must meet DC resistance of 166Ω for a 100 cm lead, 350Ω maximum change in DC resistance, and maintain ability to properly pace and sense.	8	Pass

Summary of ACUITY Steerable Design Verification Testing	Sample Size	Test Results (Pass/Fail)
Intracardiac Buckle Flex Fatigue at Proximal Electrode: After flexing in the proximal electrode zone, verify lead body conductor withstands ten years (420 million cycles) of flexing. Test is based upon minimum in-vivo intracardiac bend radius conditions. Sample must meet DC resistance of 166Ω for a 100 cm lead, 350Ω maximum change in DC resistance, and maintain ability to properly pace and sense.	8	Pass
System Compatibility		
System compatibility (1): Verify stylet can pass through the stylet guide and terminal pin with less than 0.25 lbs-force. Result max was 0.0325lbs.	12	Pass
System compatibility (2): Verify guide wire withdrawal force is 0.4lbs or less. And lead must advance over the guide wire. And guide wire must be able to be inserted. Result max was 0.25 lbs.	12	Pass
System compatibility (3): Verify stylet withdrawal force 0.4 lbs or less. And stylet must be able to be inserted into lead. And stylet must not protrude beyond the distal tip. Result max was 0.27 lbs.	12	Pass
System compatibility (4): Lead leakage current must be less than 2mA Result max was 0.051mA.	12	Pass
System compatibility (5): Verify lead meets visual, resistance and pressure test (insulation integrity).	12	Pass

The ACUITY™ Steerable Lead contains several components that are identical to devices that are commercially available from Guidant. Generally, the tests listed in the table below are needed. However, for this submission, the sponsor referenced tests from previously marketed devices that are applicable to the ACUITY™ Steerable Lead. The PMA supplement number for each referenced test appears in the table below.

Referenced Tests	
Steroid Dosage	Identical to ET3 LV-1 (P010012/S025, approved 06Aug04)
Lead Visual Inspection	Identical to ET3 IS-1 (P010012/S032, approved 24Nov04)
IS-1 Insertion/Withdrawal Force	Identical to ET3 IS-1 (P010012/S032, approved 24Nov04)
IS-1 Pin/Setscrew Deformation[1]	Identical to ET3 IS-1 (P010012/S032, approved 24Nov04)
IS-1 Dimension Inspection	Identical to ET3 IS-1 (P010012/S032, approved 24Nov04)

[1] Test was performed twice because of a bond design enhancement. Both reports were submitted with lead. (*P010012/S032, approved 24Nov04*).

Referenced Tests *(continued)*		
Low Voltage Seal Integrity	Identical to ET3 IS-1 (the enhanced bond report) (P010012/S032, approved 24Nov04)	
Lead Cap testing[2]	Identical to ET2 IS-1 for model 6623 (P010012/S024, approved 06AUG04) and ET 1 IS-1 for model 6829 (P010012/S003, approved 22Jan03)	
IS-1 Hemostasis Valve Insertion/Withdrawal Force (Dry Terminal)	Identical to ET2 IS-1 (P010012/S024, approved 06Aug04)	
IS-1 Hemostasis Valve Lead System Leak Test (Dry Terminal Pin)	Identical to ET2 IS-1 (P010012/S024, approved 06AUG04)	
IS-1 Hemostasis Valve Insertion/Withdrawal Force (Wet Terminal Pin)	Identical to IS-1 (P010012/S024, approved 06AUG04)	
IS-1 Hemostasis Valve Lead System Leak Test (wet Terminal Pin)	Identical to o ET2 IS-1 (P010012/S024, approved 06AUG04)	
Packaging and Lead Visual	Identical to RELIANCE G/SG tachy lead (P910073/S041, approved 04NOV03 P910073/S035, approved 02NOV00)	
Sterilization Assessment: A 100% Ethylene Oxide (ETO) process is used. An overkill approach based on ANSI/AAMI standard 11135-1994 "Medical Device Validation and Routine Control of ETO" is used because it ensures the probability of a microbial survivor is less than one in a million.	Identified product capable of being sterilized per the validated Guidant ethylene oxide sterilization process	
Shelf Life: Lead must meet 2-year shelf life requirement. Accelerated aging was submitted along with an assessment.	10	Pass
Safety and Risk Analysis: Hazard Analysis and Process FMEA were conducted.	Mitigations for potential hazards were reviewed and identified as acceptable	
Second Supplier		
Axial load MDVT testing was performed to verify inner coil insulation silicone tubing extruded from Helix Medical inc. conformed to axial load requirements of maximum permanent elongation = 5% and leakage current ≤ 2mA.	10	Pass

C. Animal Studies

Guidant conducted a chronic, 90-day, study to demonstrate that the ACUITY Steerable lead pacing system is safe in an animal model. ACUITY Steerable differs from the market approved EASYTRAK family of left ventricular leads because it has a stylet delivery option and a "J" shaped fixation tip. The purpose of the animal study was to (1) evaluate in vivo the mechanical and electrical performance of the lead and (2) demonstrate that the various components of the pacing lead system are functional, compatible, and safe in an animal model. The animal model chosen was a female porcine because the veins are similar in size to human, which allowed Guidant to assess lead handling and fixation appropriately.

[2] There are two lead caps for the EASYTRAK 4 STEERABLE lead.

The GLP animal study conclusion shows that the ACUITY Steerable lead can be successfully implanted with the lead delivery tools (including the soft and standard stylets) and remains fixed without dislodging or perforating and continues to provide acceptable chronic electrical performance. Chronic data further supports ACUITY Steerable system safety.

Acute animal GLP results at 28-days show all primary endpoints were successfully met:

- Mean pacing threshold was less than 3.5 volts (N=3)
- Mean pacing impedance was greater than 300 ohms (N=7)
- Mean R-wave amplitude was greater than 3mV (N=8)

Acute Observational data were also collected at 28 days:

1. Adverse Events involving the compatibility of the lead implant tools (guiding catheter, ET4 soft or standard stylet, standard guide wire or finishing wire, and handling characteristics (steerability with Stylet) of the ACUITY Steerable lead at implantation
2. Verification of the mean unipolar and bipolar impedance of ACUITY Steerable less than 2000 ohms at 28 days

And, successful *Chronic Observations* were collected at 90 days:

3. Lead integrity assessment
4. Gross tissue assessment
5. Histopathology assessment
6. Chronic Fixation that is qualitatively assessed; lead movement rate from original implant location at 90 days (±6days). Additionally, pacing thresholds, pacing impedances, R-wave amplitudes on Day 60 (± 6 days) and Day 90 (± 6 days) were measured.

The animal testing and test results were acceptable to support the safety and effectiveness of the ACUITY Steerable lead.

X. Clinical Study

Study Design

This clinical investigation was a prospective, multi-center, non-randomized study designed to demonstrate the safety and effectiveness of the ACUITY Steerable Left Ventricular lead, models 4554/4555/4556, in humans. A total of 110 patients were enrolled at 26 centers in the United States.

In all patients implanted with the ACUITY Steerable lead, the lead was connected to a CONTAK RENEWAL® 3 or CONTAK RENEWAL 3 HE, cardiac resynchronization therapy defibrillator (CRT-D) or to a CONTAK RENEWAL TR cardiac resynchronization therapy pacemaker (CRT-P).

Patient Selection

Patient Inclusion Criteria

- Must receive a commercially available Guidant CRT-P or CRT-D device
- Creatinine < 2.5 mg/dL obtained no more than two weeks prior to enrollment
- Age 18 or above, or of legal age to give informed consent specific to state and national law
- Willing and capable of providing informed consent, undergoing a device implant, participating in all testing associated with this clinical investigation at an approved clinical investigation center and at the intervals defined by this protocol
- Geographically stable residents who are available for follow-up

Exclusion Criteria

- Have a known hypersensitivity to a 1.0 mg (0.5 mg per electrode) nominal dose of dexamethasone acetate
- Have or had previous cardiac resynchronization therapy, a coronary venous pace/sense lead or attempted LV lead placement
- Have pre-existing cardioversion/defibrillation leads other than those specified in the investigational plan (unless the investigator intends to replace them with permitted cardioversion/defibrillation leads)
- Currently requiring dialysis

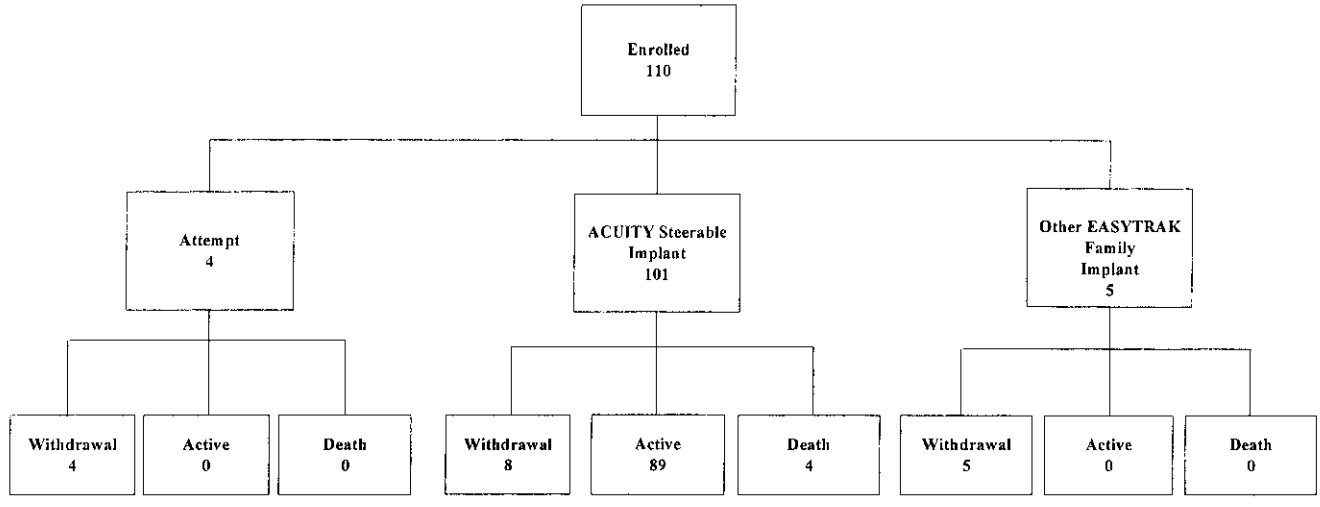
- Have had a myocardial infarct, unstable angina, percutaneous coronary intervention, or coronary artery bypass graft during the preceding 30 days prior to enrollment
- Have hypertrophic obstructive cardiomyopathy or infiltrative cardiomyopathy (e.g., amyloidosis, sarcoidosis)
- Documented life expectancy of less than six months or expected to undergo heart transplant within the next six months
- Enrolled or participating in any concurrent study without Guidant written approval, that may confound the results of this study
- Have a pre-existing unipolar pacemaker that will not be explanted/abandoned
- Have a mechanical tricuspid heart valve
- Women who are pregnant or plan to become pregnant

Note: Women of childbearing potential must have had a negative pregnancy test within seven days of enrollment.

Patient Enrollment and Follow-Up

Data was collected for a total of 110 patients enrolled in the study. All 110 patients enrolled in the study underwent an implant procedure to receive the Acuity steerable lead. 101 patients were successfully implanted. Follow-up was performed at pre-discharge, 1-month and 3-months to meet study endpoints. Patients will be followed once a quarter until study closure. **Figure 3** outlines the Patient status of the trial.

Figure 3: Patient Status



Objectives

Primary Objective 1: Safety – Lead Related Complications
Hypothesis: The ACUITY Steerable lead will be equal-to or greater-than 80% at three-month, post implant for lead-related complication-free rate; where 80% is the pre-determined one-sided 95% acceptance boundary.

Primary Objective 2: Effectiveness – Pacing Thresholds
Hypothesis: The ACUITY Steerable lead will be equal-to or greater-than 2.5 Volts at three-month, post implant for left ventricular pacing threshold when measured at 0.5ms pulse width; where 2.5V is the pre-determined one-sided 95% acceptance boundary.

Secondary Objective 1: Effectiveness – Sensed Amplitudes
Hypothesis: The ACUITY Steerable lead will be programmed to the sensing amplitude capable of detecting R-waves that is equal-to or less-than 3.0 mVolts at three-month, post implant; where 3.0mV is the pre-determined one-sided 95% acceptance boundary.

Secondary Objective 2: Effectiveness – Pacing Impedances
Hypothesis: The ACUITY Steerable lead will be tested in each possible pacing configuration and programmed to the pacing impedance that is equal-to or less-than 300 Ω, at three-month, post implant; where 300 Ω is the pre-determined one-sided 95% acceptance boundary.

Patient Demographic Information

Patient demographic information is provided in **Table 6.**

Table 6: Patient Demographics

All patients enrolled; N=110

Characteristic	Measurement	Result
Age at Implant (years)	N	110
	Mean ± SD	68.0 ± 11.6
	Range	28.7 - 84.9
Gender [N (%)]	Male	72 (65)
	Female	38 (35)
NYHA Class [N (%)]	II	1 (1)
	III	98 (89)
	IV	11 (10)
LVEF (%)	N	110
	Mean ± SD	23.5 ± 7.0
	Range	10.0 - 40.0
QRS Duration† (ms)	N	109
	Mean ± SD	153 ± 27
	Range	80 - 240
Etiology [N (%)]	Ischemic	70 (64)
	Nonischemic	40 (36)
Conduction Disorder‡ [N (%)]	Left Bundle Branch Block	76 (74)
	Nonspecific Intraventricular Delay	15 (15)
	Right Bundle Branch Block	12 (12)
Arrhythmias* [N (%)]	SVT	37 (65)
	Nonsustained VT	14 (25)
	Monomorphic VT (MVT)	5 (9)
	Nonsustained VT with inducible MVT	5 (9)
	Premature ventricular contractions	4 (7)
	Heart block	3 (5)
	Ventricular Fibrillation (VF)	3 (5)

Characteristic	Measurement	Result
	Sick sinus syndrome	2 (4)
	Conduction disorder	1 (2)
	Other**	4 (7)

†Not available for 1 pacer dependent patient
‡Conduction disorder not present in 7 patients
*Patients may appear in more than one category
**Includes 1 patient with Bradycardia, 1 patient with nonsustained accelerated ventricular rhythm, 1 patient with recurrent ventricular tachycardia, and 1 patient with both junctional escape and premature atrial contractions

Gender Bias

The gender selection in this clinical trial was completely random, and patient selection was solely based upon exclusion and inclusion criteria. Men represented 65% of the population. There was no difference in safety and effectiveness of the ACUITY Steerable lead with respect to gender.

Data Analysis and Results

Results of the primary objectives are provided in **Table 7.**

Table 7: Data Analysis and Results

Endpoint and Hypothesis	Result		Met Endpoint
Primary Safety Endpoint			
Lower one-sided 95% confidence bound of the 3-month lead-related complication-free rate > 80% [% (LB*)]	N (pts)	110	Yes
	Number of pts with complications @ 3 months	9	
	Complication-Free Rate	91.8%	
	Lower One-Sided 95% Confidence Bound	86.2%	
Primary Effectiveness Endpoint			
Upper one-sided 95% confidence bound of the 3-month pacing threshold < 2.5 V [mean (UB*)]	N (pts)	90	Yes
	3-month pacing threshold (Mean +/- SD)	1.1 +/- 0.9	
	Upper One-Sided 95% Confidence Bound	1.3	
Secondary Effectiveness Endpoints			
Lower one-sided 95% confidence bound of the 3-month R-wave amplitude > 3mV [mean (LB)]	N (pts)	80	Yes
	3-month R-wave amplitude (Mean +/- SD)	14.3 +/- 7.4	
	Lower One-Sided 95% Confidence Bound	12.9	
Lower one-sided 95% confidence bound of the 3-month pacing impedance > 300 Ohms [mean (LB)]	N (pts)	90	Yes
	3-month pacing impedance (Mean +/- SD)	644 +/- 207	
	Lower One-Sided 95% Confidence Bound	608	

*LB: Lower Bound, UB: Upper Bound.

Implant Success Rate

Table 8 shows the Acuity Steerable lead implant success rates.

Table 8: Implant Success Rate

All patients implanted or attempted with an LV lead; N=110

Left Ventricular Lead	Number of Patients Undergoing Procedure	Number of Patients Successfully Implanted	Success Rate
ACUITY STEERABLE LV lead success rate	110	101	91.8%
EASYTRAK family success rate*	110	106	96.3%

*The EASYTRAK family implant success included patients who received any lead in the EASYTRAK family (EASYTRAK, EASYTRAK 2, EASYTRAK 3 and ACUITY steerable).

Lead Placement

The final implant positions of the Acuity Steerable lead are shown in **Table 9**

Table 9: Acuity Steerable Lead Placement

All patients implanted with an Acuity Steerable lead; N=101

Position from RAO View	Position from LAO View				
	Anterior	Lateral	Posterior	Other*	Total
Basal	1 (1.0%)	9 (8.9%)	1 (1.0%)	1 (1.0%)	12 (11.9%)
Mid	2 (2.0%)	74 (73.3%)	5 (5.0%)	2 (2.0%)	83 (82.2%)
Apical	0 (0.0%)	3 (3.0%)	1 (1.0%)	1 (1.0%)	5 (5.0%)
Other*	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	1 (1.0%)
Total	**3 (3.0%)**	**86 (85.1%)**	**8 (7.9%)**	**4 (4.0%)**	**101 (100.0%)**

*Other RAO position reported as posterior/lateral (1); other LAO positions reported as posterior/lateral (3) and lateral/apical (1).

Device Failures and Replacements

There were seven (7) ACUITY Steerable lead replacements and no device failures for the clinical trial. Summary of the replacements at data cutoff included two (2) that were replaced with another ACUITY Steerable lead and five (5) that were replaced with a different LV lead.

XI. Conclusions Drawn from the Studies

Safety of the ACUITY™ Steerable lead was characterized by evaluating the lead in bench and animal studies, and by examining survival from lead-related complications and events in a clinical trial. Survival from all complications and events at 3 months post-implant was determined to be acceptable in this study. All primary objectives were met.

Effectiveness of the ACUITY™ Steerable lead was characterized by evaluating the lead in bench and animal studies, and by examining pacing and sensing performance through three months post-implant in a clinical trial. All primary and secondary objectives were met.

Therefore, 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.

XII. Panel Recommendation

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory Systems Panel, and FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH Decision

FDA issued an approval order on April 13, 2007.

The applicant's manufacturing facility was inspected and was found to be in compliance with the Quality System Regulation (21 CFR 820).

XIV. Approval Specifications

Directions for Use: See labeling

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

Postapproval Requirements and Restrictions: See approval order.

APPENDIX A: All Adverse Events

Table 10: Clinical Observation and Complications Summary

All patients implanted or attempted; N=110
Total device months = 984
Includes all adverse events reported through March 21, 2006

		Complications		Observations	
Adverse Event	**Number Of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Total Adverse Events	**157 (65)**	**34.5 (38)**	**6.6 (65)**	**44.5 (49)**	**9.3 (92)**
ACUITY Steerable Related Events (N=101)					
Coronary venous dissection	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.1 (1)
Dislodgment - Elevated threshold - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Dislodgment - Extracardiac stimulation - LV	4 (4)	2.0 (2)	0.2 (2)	2.0 (2)	0.2 (2)
Dislodgment - Multiple signs - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Dislodgment - No reported signs - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Dislodgment - Unable to capture - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Elevated threshold - LV	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.2 (2)
Extracardiac stimulation - LV	19 (17)	1.0 (1)	0.1 (1)	15.8 (16)	1.9 (18)
Subtotal ACUITY Steerable Related Events	**34 (29)**	**9.9 (10)**	**1.1 (11)**	**19.8 (20)**	**2.4 (23)**
PG Related Events (N=106)					
Elevated DFT - Defibrillation	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Extracardiac stimulation - Daily impedance testing	3 (3)	0.0 (0)	0.0 (0)	2.8 (3)	0.3 (3)
Hematoma - Pocket (> 30 days post-implant)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Infection (> 30 days post-implant)	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Migration	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Pacemaker-mediated tachycardia (PMT)	3 (3)	0.0 (0)	0.0 (0)	2.8 (3)	0.3 (3)
Psychological effect due to device therapy	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Subtotal PG Related Events	**12 (9)**	**0.9 (1)**	**0.2 (2)**	**7.5 (8)**	**1.0 (10)**
RA Lead Related Events (N=106)					
Dislodgment - Unable to capture - RA	2 (2)	1.9 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Elevated threshold - RA	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Oversensing - RA	2 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.2 (2)

		Complications		Observations	
Adverse Event	Number Of Events (Number of Patients)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Unable to capture - RA	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Subtotal RA Lead Related Events	**6 (4)**	**2.8 (3)**	**0.3 (3)**	**0.9 (1)**	**0.3 (3)**
RV Lead Related Events (N=106)					
Dislodgment - Elevated threshold - RV	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Elevated threshold - RV	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Subtotal RV Lead Related Events	**2 (2)**	**1.9 (2)**	**0.2 (2)**	**0.0 (0)**	**0.0 (0)**
Procedure Related Events (N=110)					
Adverse reaction - General	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Adverse reaction - Hypotension	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Chest pain	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Hematoma - Pocket (<=30 days post-implant)	6 (6)	0.9 (1)	0.1 (1)	4.5 (5)	0.5 (5)
Inappropriate VF sensing - Noise	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
LV Lead Insulation Damaged	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
LV Lead Insulation Damaged During Procedure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Post-surgical wound discomfort	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Psychological effect due to recall	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.2 (2)
RV and LV leads transposed on header	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Thrombus	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Subtotal Procedure Related Events	**18 (16)**	**5.5 (6)**	**0.6 (6)**	**10.0 (11)**	**1.2 (12)**
Protocol Testing Related Events (N=110)					
Extracardiac stimulation - LV	3 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.3 (3)
Subtotal Protocol Testing Related Events	**3 (2)**	**0.0 (0)**	**0.0 (0)**	**1.8 (2)**	**0.3 (3)**
Cardiovascular Related Events (N=110)					
Atrial fibrillation (AF)	5 (4)	0.9 (1)	0.1 (1)	2.7 (3)	0.4 (4)
Atrial flutter	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Cerebrovascular accident (CVA)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Chest pain - Heart failure	3 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.3 (3)
Chest pain - Ischemic	4 (3)	0.9 (1)	0.1 (1)	1.8 (2)	0.3 (3)
Chest pain - Other	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Chronotropic incompetence	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Dizziness	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)

		Complications		Observations	
Adverse Event	Number Of Events (Number of Patients)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Dizziness - Heart failure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Dyspnea - Heart failure	4 (4)	2.7 (3)	0.3 (3)	0.9 (1)	0.1 (1)
Gastrointestinal - Heart failure	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Hypotension - Heart failure	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.2 (2)
Multi-system failure - Heart failure	3 (3)	2.7 (3)	0.3 (3)	0.0 (0)	0.0 (0)
Multiple heart failure symptoms	16 (14)	10.0 (11)	1.2 (12)	3.6 (4)	0.4 (4)
Multiple symptoms	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Myocardial infarction	2 (2)	1.8 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Nonsustained ventricular tachycardia (NSVT)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Other SVT (AVRT, AVNRT, EAT etc.)	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.2 (2)
Peripheral edema - Heart failure	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Prophylactic treatment	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Pulmonary embolism (PE)	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Renal insufficiency - Heart failure	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Sinus tachycardia	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Syncope	3 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.3 (3)
Ventricular fibrillation (VF)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Ventricular tachycardia (VT)	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Subtotal Cardiovascular Related Events	**63 (36)**	**17.3 (19)**	**2.9 (29)**	**20.9 (23)**	**3.5 (34)**
Subtotal Non-cardiovascular Related Events	**19 (11)**	**6.4 (7)**	**1.2 (12)**	**4.5 (5)**	**0.7 (7)**