Summary of Safety and Effectiveness Data

1.0 General Information

Device Generic Name	Electrophysiology Ablation Catheter RF Ablation Generator
Device Trade Name	Therapy™ Cool Path™ Ablation Catheter IBI 1500T9 Radiofrequency Generator
Applicant's Name and Address	Irvine Biomedical, Inc. ("IBI") A St. Jude Medical company 2375 Morse Ave. Irvine, CA 92614
Date of Panel Recommendation	None
Premarket Approval Application (PMA) #	P060019
Date Notice of Approval of Application	March 16, 2007

2.0 Indication for Use

The Therapy™ Cool Path™ Ablation Catheter is intended for use with a compatible external infusion pump and the IBI 1500T9 Radiofrequency (RF) Generator at a maximum of 50 watts. The catheter is intended for creating endocardial lesions during cardiac ablation procedures (mapping, stimulation and ablation) for the treatment of typical atrial flutter.

The IBI 1500T9 RF Generator is intended for use with compatible St. Jude Medical temperature controlled ablation catheters for creating endocardial lesions to treat cardiac arrhythmias (i.e. supraventricular tachycardias, and atrial flutter). The generator is internally limited to 50 watts when used with the Therapy™ Cool Path™ catheters. A compatible external infusion pump must be connected when used with Therapy™ Cool Path™ catheters.

3.0 Contraindications

Do not use the Therapy™ Cool Path™ Ablation Catheter:

- Patients with active systemic infection;
- If the patient has with intracardiac mural thrombus or has had a ventriculotomy or atriotomy within the preceding four weeks.

4.0 Warnings and Precautions

The warnings and precautions can be found in the Therapy™ Cool Path™ Ablation Catheter and the IBI 1500T9 RF Generator labeling.

5.0 Device Description

The Therapy™ Cool Path™ Ablation Catheter is a sterile, single use 7F catheter constructed of thermoplastic elastomer material and noble metal electrodes. This catheter has a through-lumen connected to open port at the tip electrode for heparinized saline irrigation during the ablation procedure. The tip curvature may be manipulated by the thumb control mechanism located in the handle at the proximal end of the catheter. The catheter is available in four distal curve configurations.

Therapy™ Cool Path™ Ablation Catheter Specifications

Feature	Specification	
Catheter Diameter	7 French	
Catheter Usable Length	110 cm (approximate)	
Number of Electrodes	Four (1 Ablation and 3 Diagnostic)	
Tip Electrode	4 mm with radial irrigation holes	
Band Electrodes	Three, 2 mm width	
Interelectrode Spacing	2mm-5mm-2mm	
Temperature Sensor	Thermocouple, Type T	
Curve Type	Steerable, Uni-directional	
	1304-CP-7-25-M	1.26" (3.2 cm) Curve Diameter
	1304-CP-7-25-L	1.69" (4.3 cm) Curve Diameter
	1304-CP-7-25-XL	1.97" (5.0 cm) Curve Diameter
	1304-CP-7-25-FL	1.22" (3.1 cm) Curve Diameter
Electrical Connector	Redel type	
Fluid Connector	Luer type	

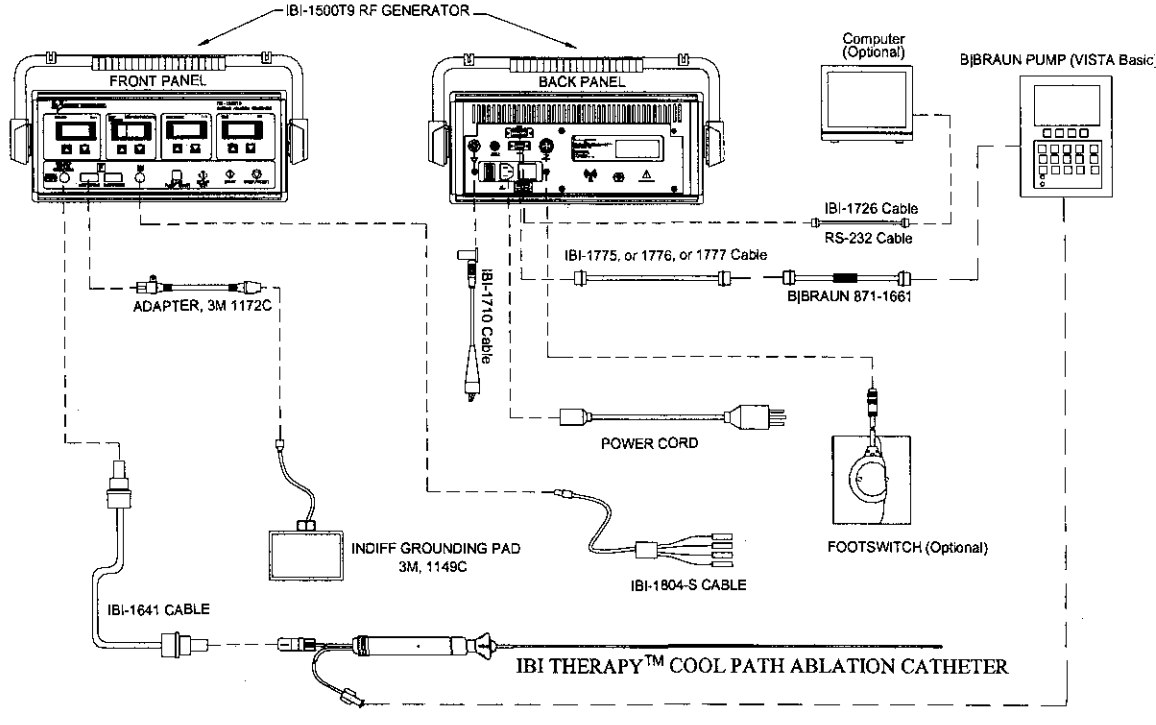
The IBI 1500T9 RF Generator is a microprocessor-controlled RF generator that produces a continuous unmodulated radio frequency (RF) power output of 485 kHz. The front panel displays power output (W), tip temperature (°C), tissue impedance (Ω), and time (s). The generator display incorporates a visual indication to show whether a Cool Path™ catheter and a compatible infusion pump are connected and initialized. The physician may establish settings for the following parameters: target tip temperature, maximum impedance, maximum power output, and ablation time. The maximum power output can be set up to 50 Watts when a Therapy™ Cool Path™ catheter is connected. The power output is regulated by the measured tip temperature, and is limited to the user selected maximum power output. The generator has built-in safety features, which include automatic power shut-offs for power, impedance and temperature. When using with a Therapy™ Cool Path™ Ablation Catheter, the generator will also shut off if the interconnected compatible infusion pump alarms. Refer to the IBI 1500T9 RF Generator instructions for use for a list of compatible infusion pumps. In addition to a compatible infusion pump, other required and optional accessories include:

- IBI 1770 series and IBI 1726 cables for connecting the IBI 1500T9 RF Generator to the compatible infusion pump
- IBI 1804-S cable for electrogram output

- IBI 1641 cable for connecting the IBI 1500T9 RF Generator to the Therapy™ Cool Path™ Catheter
- IBI 1710 cable for grounding the IBI 1500T9 RF Generator chasis
- Commercially available indifferent grounding pad and cable
- Optional footswitch
- Optional computer for logging data and ablation parameters and IBI 1726 connecting cable
- Optional 1500T extender module (20 foot extension connector)

The device utilizes non-volatile, preprogrammed firmware. During development, the firmware was tested independently and then integrated into the hardware and tested at the system level.

SYSTEM SET UP DIAGRAM WITH B|BRAUN VISTA BASIC PUMP



6.0 Alternate Practices and Procedures

Therapeutic alternatives for patients with typical (Type I) atrial flutter include direct surgical ablation, irrigated and non-irrigated RF catheter ablation with other approved diagnostic/ablation catheters, use of drugs for arrhythmia control, and anti-arrhythmia pacing.

7.0 Marketing History

Neither the Cool Path™ catheter nor the IBI 1500T9 RF Generator has been previously marketed in the United States. Therapy™ Cool Path™ catheters and the IBI 1500T series generators have been marketed internationally including Europe, Asia, and Australia. Neither the catheter nor the generators have been withdrawn from market in any country for any reason related to safety and effectiveness.

8.0 Potential Adverse Effects of Device on Health

Potential Adverse Events

Potential adverse events that maybe associated with catheterization and/or cardiac ablation include the following:

- Abnormal vision
- Adult Respiratory Distress Syndrome (ARDS)
- Air embolism
- Anaphylaxis
- Anemia
- Allergic reaction (anesthesia)
- Arrhythmias
- AV fistula
- Cardiac perforation/tamponade
- Cardiac thromboembolism
- Cerebrovascular accident (CVA)
- Chest pain/discomfort
- Complete heart block
- Component damage to ICD or implantable pacemaker
- Congestive heart failure/exacerbation
- Coronary artery spasm
- Death
- Dislodgement of implantable cardioverter defibrillator or permanent pacing leads
- Dizziness
- Endocarditis
- Esophageal injury (fistula)
- Exacerbation of pre-existing atrial fibrillation
- Expressive aphasia
- Heart Failure
- Hemothorax
- Hypoxia/shortness of breath
- Increased phosphokinase level
- Infections/sepsis
- Laceration
- Local hematomas/ecchymosis
- Myocardial infarction
- Neck/pain/groin pain
- Obstruction or perforation or damage to the vascular system
- Palpitations
- Pericardial effusion
- Pericarditis
- Phrenic nerve damage
- Pleural effusion
- Pneumonia
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Radiation injury
- Respiratory Depression
- Seizure
- Skin burns
- Syncope/near syncope
- Temporary complete heart block
- Thrombi
- Thromboembolism
- Transient ischemic attack (TIA)
- Unintended (in)complete AV, sinus node or other heart block or damage
- Valvular damage/insufficiency
- Vascular bleeding
- Vasovagal reactions
- Ventricular tachycardia
- Worsening chronic obstructive pulmonary disease

Please refer to Section 10.0 – Summary of Clinical Studies for information on the adverse events observed in the clinical study.

9.0 Summary of Nonclinical Laboratory Studies

***In vitro* testing**

A series of *in vitro* bench tests were conducted based upon the FDA guidance document, "Cardiac Ablation Preliminary Guidance", March 1995 to verify device conformance to the functional requirements defined in the product specifications. The requirements of ISO 10555-1 for intravascular catheters were used where applicable. The integrity of assembled components and the proper function of the ablation catheter for its intended use were confirmed through specific tests designed to test physical and performance characteristics of the device. A summary of the tests performed on the ablation catheter is presented in the table that follows.

	Test	Requirement	Result
Reliability Tests	Catheter Recognition and Parameter Limits	Verify repeatable, accurate detection of Therapy™, Therapy™ Dual 8™, and Therapy™ Cool Path™ catheters with corresponding default settings and maximum settings of power, temperature and ablation time using three of each type of catheter.	Pass
	Performance Reliability	Electrical continuity on 10 catheters after 10 cycles of simulated RF ablation	Pass
	Torsional Testing (joint integrity)	No tip and tube joint failure on 15 catheters after 1-2 shaft rotations with tip fixed	Pass
	Catheter Tensile Testing (Bond Strength)	Tensile strength of tip-tubing bond ≥ 3.37 lbs on 30 subassemblies. Measure tensile strength after deflection/flexion on 10 catheters	Pass
	Handle/Shaft Tensile Strength	Tensile strength of catheter shaft to handle joint ≥ 3.37 lbs on 10 catheters	Pass
	Deflection Fatigue and Flexion Fatigue (Catheter Integrity after repetitive Deflection and Flexion cycles)	Electrical continuity with resistance ≤ 7.0 ohms, tensile strength ≥ 3.37 lbs and no lumen leakage at 25 psi after 60 repetitive deflection and 60 flexion cycles on 10 catheters	Pass
	Dielectric Strength	No breakdown after 500 VAC for 60 sec. between conductors on 10 catheters	Pass
	Performance Reliability	No mechanical breakdown after multiple applications of RF energy on 13 catheters	Pass

	Test	Requirement	Result
	Fluid line backpressure (to prevent false pump alarms)	Backpressure did not exceed 15 psi or cause false alarms on 12 catheters	Pass
Mechanical Tests	Steering (Simulated pull - straight and curved) post 8 hour soak	Measure catheter pull force through simulated arch straight and deflected on 10 catheters	Pass
	Bending	Measure shaft deflection with force applied at midpoint on 10 catheters	Pass
	Buckling Load (Buckling Force)	Buckling load ≤ 200 grams under simulated use conditions on 15 catheters	Pass
	Radiopacity	Fluoroscopic visualization of catheters under simulated clinical conditions on 6 catheters	Pass
	Torque/Twist Angle	No electrical and mechanical failure at 180°-720° twist angle on 15 catheters	Pass
	Leak Pressure Test	No leaks or tubing bond failure at 25 psi on 30 subassemblies	Pass
Electrical Tests	RF Impedance	≤ 300 ohms impedance at operating frequency on 6 catheters	Pass
	Noise	Clear EKG signal during simulated use on 10 catheters	Pass
	Stimulation (Pacing)	Using PSA and EKG monitor, stimulate the heart and measure output levels at 120 bpm on 2 catheters	Pass
	Mapping	Clearly visible and identifiable EKG signals under simulated use on 10 catheters	Pass
	Electrical Resistance	DC resistance ≤ 7 ohms of conductor circuit on 13 catheters	Pass
	Leakage Current post 8 hour soak	Electrical leakage ≤ 10 µA at 400VDC on 10 catheters	Pass
	AC Impedance	Measure AC impedance at 5 kHz and verify ≤ 1.0% signal loss on 10 catheters.	Pass
	High Frequency Leakage Current	≤ 4.02 mA/cm leakage at 400 Volts at 485 KHz in saline bath on 10 catheters	Pass
	Thermal Response and Accuracy	± 3° C accuracy of temperature sensor and < 3 sec sensor response time on 10 catheters	Pass

	Test	Requirement	Result
Cable	Connector Engagement and Separation Force	Tensile force to engage and disengage the connector is 3.0 lbs or less on 15 samples	Pass
	Accessory Cable Flex Fatigue	Maintain electrical continuity (resistance measurement) after 50 flexion cycles on 15 samples	Pass
	Dielectric Strength Breakdown	No dielectric breakdown at 500VAC on 10 samples	Pass
	Cable Tensile Pull Test	No breaks under 10.0 lbs on 15 samples	Pass

In summary, the tested catheters successfully met the established acceptance criteria.

Biocompatibility testing

The patient contacting materials of the Therapy™ Cool Path™ Ablation Catheter were tested using a representative catheter in accordance with ISO 10993 for external communicating devices in contact with circulating blood for limited/transient duration. Biocompatibility testing was performed to GLP standards and in accordance with applicable parts of ISO 10993 and establishes biocompatibility and material safety as used in the device.

Comparison of Test Articles to Therapy™ Cool Path™ (Patient Contact Materials)

Component	Therapy™ Cool Path™ Material	Ultrasound Material Test Article	Luma-Cath Material Test Article	Patient Contact
Extruded Shaft	Pebax™ polyether block amide thermoplastic	Pebax™ polyether block amide thermoplastic and	Pebax™ polyether block amide thermoplastic	Direct Tissue and Blood
		Urethane		
Tip	Platinum/Iridium (90/10%)	Platinum/Iridium (90/10%)	Platinum/Iridium (90/10%)	Direct Tissue and Blood
Band Electrodes	Platinum/Iridium (90/10%)	Platinum/Iridium (90/10%)	Platinum/Iridium (90/10%)	Direct Tissue and Blood
Adhesive	Urethane	Urethane	Urethane	Indirect
Tip Adhesive	Cyanoacrylate	Cyanoacrylate	Cyanoacrylate	Direct
Lumen (internal)	Polyimide	Polyimide		Fluid Path indirect

Component	Therapy™ Cool Path™ Material	Ultrasound Material Test Article	Luma-Cath Material Test Article	Patient Contact
Balloon		Urethane		N/A to Cool Path™
Luer	Polycarbonate	Polycarbonate		Fluid Path indirect

Biocompatibility Testing Performed

Biological Effect	Test	Method	Result
Acute toxicity	Cytotoxicity	ISO 10993-5, 1X MEM Extract	Pass
Sensitization	Sensitization	ISO 10993-10, maximization in guinea pigs (dermal contact) or	Pass
	Sensitization	ISO 10993-10, Local Lymph Node Assay (in mouse)	Pass
Irritation or Intracutaneous Reactivity	Intracutaneous Reactivity	ISO 10993-10, reactivity in rabbits	Pass
Systemic Toxicity	Systemic Toxicity	ISO 10993-11, intravenous and intraperitoneal routes in mice	Pass
Hemocompatibility	Hemolysis	ISO 10993-4, In-vitro procedure	Pass
	In-Vivo Thromboresistance	ISO 10993, In-vivo (dog, venous implant)	Pass
	Plasma Recalcification	ISO 10993-4, In-vitro procedure	Pass
Pyrogenicity	Rabbit Pyrogen Test	ISO 10993-11, Material-Mediated Rabbit Pyrogen	Pass

Packaging/shelf life/sterilization testing

Package sealing was validated and packaging integrity was performed after subjecting the packages to shipping and distribution stresses according to International Safe Transit Association procedure ISTA 2A Transportation Protocol. Real-time and accelerated aging were performed to support the shelf-life of three years for the catheter.

The catheter is sterilized with ethylene oxide (EtO) gas. The sterilization process was validated in accordance with recognized standard ISO 11135, Medical devices -- Validation and routine control of ethylene oxide sterilization. The process validation demonstrated that the sterilization process renders products sterile to a sterility assurance level (SAL) of 10^{-6}. Residual levels for EtO and ECH met the requirements for limited exposure devices in accordance with recognized standard ISO 10993-7 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals.

***In vivo* animal studies**

The safety and effectiveness of the Therapy™ Cool Path™ Ablation Catheter with a 1500T series RF Generator and external infusion pump was demonstrated in a canine model. Five (5) dogs were used in the acute portion of the study, and five (5) dogs were used for the chronic study. The catheter handled adequately, was able to acquire intracardiac electrograms and produced area specific lesions as expected.

Electrical Safety and EMC Testing

Electrical Safety testing and Electromagnetic compatibility (EMC) testing were performed on the IBI 1500T9 RF Generator in accordance with the applicable requirements of IEC 60601. Testing was also performed in accordance with the applicable IEC 60601 requirements for high frequency surgical equipment with a Cool Path™ catheter connected. The device passed the acceptance criteria for the specified tests.

IBI 1500T9 RF Generator Software

Software validation and verification testing was conducted to demonstrate that the software-controlled IBI 1500T9 RF Generator adequately detects, controls, and interfaces with the connected catheter and compatible infusion pump.

10.0 Summary of Clinical Studies

10.1 Objectives

A prospective, randomized multicenter study of RF ablation was conducted to demonstrate the Safety and Effectiveness of the Therapy™ Cool Path™ Ablation Catheter used in conjunction with the IBI 1500T9 RF Generator.

10.2 Study Design

The study was a prospective, randomized, non-blinded, multi-center controlled clinical study of patients requiring treatment for typical atrial flutter. Follow-up evaluations occur at 10 days (allowable window of ±3 days) and 3 months (allowable window of ±2 weeks) and in the interim if required. The study was designed to demonstrate that safety and effectiveness of the investigational device (Cool Path, also referred to as the experimental or study device) was equivalent (not inferior) to that of the control device (i.e., legally marketed ablation catheters approved for the treatment of typical atrial flutter).

All patients were treated with RF ablation. Two-thirds of the patients were treated with the study device and one-third of the patients were treated with the control device.

Data collection included basic demographics, presenting signs and symptoms, characteristics of the index arrhythmia, procedural parameters (ablation duration, impedance, power, temperature, and radiation entrance dose exposure), cardiac medications, treatment outcome, adverse events and assessments for recurrence of the treated arrhythmia.

Clinical Endpoints

The primary safety endpoint was based upon serious adverse cardiac events occurring within 7 days of the index procedure ("Major Complications").

The primary effectiveness endpoint was acute procedural success defined as the creation of bi-directional conduction block and non-inducibility of typical atrial flutter at least 30 minutes following therapeutic intervention using only the randomized investigational or control catheter.

The secondary effectiveness endpoint was chronic clinical effectiveness defined as a lack of atrial flutter recurrences at three months follow-up.

10.3 Subjects Studied

Table 1 – Subject Accountability

Status	Number of Investigational Arm Subjects	Number of Control Arm Subjects
Screened	326	
Discontinued Prior to Randomization	8	
Randomized	210	108
Discontinued After Randomization, but Prior to Ablation:	36	18
Non-protocol arrhythmia	22	16
Other screen failure		1
Withdrew consent	3	1
Physician discretion	10	
Equipment not available	1	
Treated	174	90
Acute Failures	13	3
Acute Success	161	87
Death, post-ablation	3	
Lost to Follow-up	9	6
Chronic (3 month) follow-up available	149	81
Chronic Failure	5	2
Chronic Success	144	79

10.4 Demographics

A total of 264 patients (174 Cool Path™, 90 Control) were treated at twenty-two (22) participating investigational sites. Of 174 patients randomized to be treated with the investigational device, 81.0% were male (141/174) with a mean age of 67.7 years and an average weight of 204 pounds. Of 90 patients randomized to be treated with the control device, 80.0% were male (72/90) with a mean age of 66.1 years and an average weight of 204 pounds. There was no significant difference between the treatment groups with respect to age, gender or weight.

Cardiac history (medical and surgical) is summarized below. Coronary artery disease (CAD) was present in 44.8% of investigational group subjects and 33.3% of control group

subjects. Atrial fibrillation was present in nearly half of the subjects (48.9% investigational group, 44.4% control group). Prior coronary artery interventions were reported in 31.6% of investigational group subjects and 23.3% of control group subjects. Pacemaker or ICD Implants were present in 16.1% of investigational group subjects and 10.0% of control group subjects. There were no significant differences between the groups with respect to cardiac history, with the exception of CAD which occurred at a higher rate in the investigational group.

10.5 Procedural Data

Study Group

In 173 (of 174) investigational arm subjects, at least one attempt was made to deliver RF energy with the Study Device. One (1) subject was treated with a legally marketed, non-study device.

Energy was applied a total of 3967 times with an average of 23.1 (±16.1) applications per subject (range 3-104). Energy deliveries in the investigational group were limited by protocol to a maximum duration of 60 seconds. There was no such limit for the control group.

Mean procedure time (treatment phase with the study catheter plus mapping time) was 133.71 (±69.0) minutes (range 45-528). Mean RF time was 19.95 (±14.2) minutes (range 3.0-91.7) and the mean fluoroscopy time was 31.4 (±24.5) minutes (range 4.0-134.0).

The mean duration of energy delivery (per application) was 52.2 (± 15.3) seconds (range 0-60) at an average temperature 37.3 (±3.7) degrees (range 0-50) and average power of 29.8 (±7.5) watts (range 0-45). Average impedance per application was 94.3 (±16.2) ohms (range 0-330).

Three (3) deaths were reported among 174 subjects treated with the investigational device, as described below:

- One subject was an 85 year old female with a history of atrial fibrillation (AFIB), coronary artery disease, pacemaker insertion (2004) and congestive heart failure. The ablation procedure was uneventful resulting acute success. After ablation was complete, a non target arrhythmia was still present (right atrial posterior wall "scar" flutter). The device performed as expected. The patient was hospitalized 44 days following the procedure and treated for CHF. The patient remained in the hospital with continued respiratory distress that deteriorated into cardio/pulmonary arrest and the patient died at 67 days following the procedure.

- The second subject was a 48 year old male with a history of CHF, and non-ischemic cardiomyopathy. The procedure for the study arrhythmia was performed without event resulting in acute success. After RF ablation was complete, a transient non-sustained atrial flutter was present. The device performed as expected. Thirty-three (33) days following the ablation procedure, the patient suddenly collapsed at work and was pronounced dead on arrival at a local hospital from an acute coronary event.

- The third subject was a 65 year old male with a history of hypertension and Crohn's disease. The procedure for the study arrhythmia was performed without event resulting in acute success. Forty five days (45) following the procedure, the patient was admitted to the hospital with pancytopenia and was diagnosed of lymphoma. The patient was treated with chemotherapy and died nineteen days (19) later secondary to an infection related to the pancytopenia.

Control Group

At least 1 attempt was made to deliver RF energy for the 90 control subjects. Of these 90 subjects, 82 were treated with a non-irrigated system while 8 were treated with an open irrigated system.

Energy was applied a total of 1057 times with an average of 11.8 (±9.3) applications per subject (range 1-66). The mean duration per application (unrestricted by protocol) was 74.3 (± 48.5) seconds (range 0-390).

Mean procedure time (treatment phase with the control catheter plus mapping time) was 96.5 (±39.4) minutes (range 42-263). Mean RF time per procedure was 14.5 (±10.5) minutes (range 2.5-52.6) and the mean fluoroscopy time was 21.0 (±19.6) minutes (range 4.1-171.0).

Mean energy delivery per application for all catheter types was 43.9 (± 18.9) watts (range 0 to 101.0) at an average temperature 50.6 (± 8.4) degrees Celsius (range 0 to 78.0) with an average impedance of 90.7 (± 40.7) ohms (range 0 to 478.0).

No deaths were reported in the control group.

Procedural Data Comparison

A comparison of procedural parameters is provided in Table 2. Differences between the investigational and control groups were statistically significant for procedure time, power per application, temperature, fluoroscopy time, impedance and total fluid administered. This disparity was expected due to restrictions on the investigational device dictated by the protocol.

Per protocol, the maximum duration per application was 60 seconds for the investigational group. For the control group, there was no such restriction and durations as high as 390 seconds were applied. The limitation in duration is the primary reason for the greater number of RF applications which in turn led to increased procedure times for the investigational device.

Differences in procedural parameters such as temperature, power, impedance and total fluid are related to the operation of the open irrigation system used in the investigational group, compared to non-irrigated systems used to treat the 82 patients in the control group. Lower power and temperature as well as higher impedance reported in the investigational group are consistent with current literature results comparing irrigated versus non-irrigated systems.

Table 2 - Comparisons of Procedural Parameters

Measure	Investigational Group (n=174)	Control Group[1] (n=90)
# OF APPLICATIONS PER PROCEDURE	23.1 ± 16.1 (n=173)	11.8 ± 9.3 (n=90)
RF TIME (Min.) PER PROCEDURE	20.0 ± 14.2 (n=173)	14.5 ± 10.5 (n=90)
FLUOROSCOPY TIME (Min.) PER PROCEDURE	31.4. ± 24.5 (n=173)	21.0 ± 19.6 (n=89)
PROCEDURE TIME (Min.) PER PATIENT	133.7 ± 69.0 (n=170)	96.5 ± 39.4 (n=90)
RF TIME (Sec.) PER APPLICATION	52.2 ± 15.3 (n=3967)	74.3 ± 48.5 (n=1057)
ENTRANCE SKIN EXPOSURE DOSE (Gy) PER PATIENT	$1.2x10^{-2} \pm 2.0x10^{-2}$ (n=165)	$8.2x10^{-3} \pm 1.2x10^{-2}$ (n=85)
TEMPERATURE (°C) PER APPLICATION	37.3 ± 3.7 (n=3961)	50.6 ± 8.4 (n=1043)
POWER (Watts) PER APPLICATION	29.8 ± 7.5 (n=3962)	43.9 ± 18.9 (n=1051)
IMPEDANCE (Ohms) PER APPLICATION	94.3 ± 16.2 (n=3962)	90.7 ± 40.7 (n=1049)
TOTAL FLUID ADMINISTERED (ml)	1021.6 ± 561.8 (n=172)	529.9 ± 389.9 (n=83)

[1] Includes both irrigated (8) and non-irrigated (82) catheters

10.6 Results

Effectiveness:

Of the 264 treated subjects, there were 248 acute successes (161 investigational group, 87 control group) and sixteen (16) acute failures (13 investigational group, 3 control group). The acute procedural success rate was 92.53% (161/174) for the investigational group versus 96.67% for the control group (87/90). The upper 95% confidence limit (UCL) for the difference between treatment groups was 8.66%. The UCL was less than the prespecified non-inferiority margin of 10%. Thus, the pivotal study demonstrates that the Therapy™ Cool Path™ Catheter System is equivalent (non-inferior) to currently marketed devices with respect to effectiveness for its intended use.

Safety:

Of the 264 treated subjects, there were twenty-two (22) major complications (14 investigational, 8 control) in twenty (20) treated subjects (12 investigational, 8 control). No unanticipated adverse device effects were reported in either group. The rate of major complications was 6.90% (12/174) for the investigational group versus 8.89% for the control group (8/90). The UCL for the difference between treatment groups was 3.87%.

The UCL was less than the prespecified non-inferiority margin of 10%. Thus, the pivotal study demonstrates that the Therapy™ Cool Path™ Catheter System is equivalent (non-inferior) to currently marketed devices with respect to safety for its intended use.

Observed Adverse Events:

A "Major Complication" refers to a serious, cardiac adverse event within 7 days of the index procedure. A total of twenty-two (22) major complications (14 investigational, 8 control) were reported in twenty (20) treated subjects (12 investigational, 8 control). These complications are tabulated in Tables 3 (investigational group) and 4 (control group).

Table 3 – Major Complications (Investigational Group)

No of Subjects	Event	Days Post-ablation
1	RECURRENT AFIB, TX REQ	2
1	RECURRENT AFIB, TX REQ	6
1	CHEST PAIN, NON-ISCHEMIC, HOSP REQ	1
1	AFIB, TX REQ	7
1	AFIB, HOSP EXTENDED	1
1	CHEST PAIN, HOSP REQ	2
1	AFIB, TX REQ	2
1	PULMONARY EMBOLISM	7
1	CHEST PAIN, UNK ETIOLOGY, HOSP OBSERVATION	1
1	RECURRENT AFIB, TX REQ	1
	BRADYCARDIA, PACEMAKER REQ	7
1	AFIB, TX REQ	1
	BRADYCARDIA, PACEMAKER REQ	7
1	HEART BLOCK PACEMAKER REQ	0
"Major Complications" include all serious, cardiac adverse events within seven (7) days of the index procedure.		

Table 4 - Major Complications (Control Group)

No of Subjects	Event	Days Post-ablation
1	RECURRENT AFIB, HOSP REQ	0
1	ACUTE PERICARDITIS	1
1	HYPOTENSION, TX REQ	0
1	MI (NON-STE)	2
1	INDUCED ATRIAL TACHYCARDIA TX W/RX	0
1	WORSENING CHF, HOSP EXTENDED	0
1	CAD, SURGERY REQ	0
1	PULMONARY CONGESTION	0
"Major Complications" include all serious, cardiac adverse events within seven (7) days of the index procedure.		

Secondary Effectiveness Endpoint:

Of the 161 subjects that had acute procedural success, there were 149 subjects in the investigational group that were seen at the three months follow-up. There were 9 subjects lost to follow up and three subjects in this group died prior to three months post ablation procedure. There were 5 subjects with recurrence of typical atrial flutter. 144/149 subjects (96.6%) were documented to have chronic success. 117/149 subjects (78.5%) were free from recurrence and anti-arrhythmic drug changes.

Of the 87 subjects that had acute procedural success , there were 81 subjects in the control group that were seen at the three months follow-up. There were 3 subjects lost to follow up, 1 subject failed to comply, 1 subject withdrew and 1 subject removed from the data due to treatment with a non-protocol catheter. There were 2 subjects with a recurrence of typical atrial flutter. 79/81 subjects (97.5%) were documented to have chronic success. 69/81 subjects (85.2%) were free from recurrence and anti-arrhythmic drug changes.

11.0 Conclusions Drawn From Studies

Preclinical testing demonstrates that the Therapy™ Cool Path™ Cardiac Ablation Catheter should maintain mechanical and electrical integrity, and materials which contact patients are biocompatible under the proposed conditions for use. Preclinical testing also demonstrates that the IBI 1500T9 RF Generator maintains electrical safety, electromagnetic compatibility, and that the software operates as designed. Bench testing has established an acceptable degree of energy delivery, accuracy and control.

Clinical data submitted under PMA P060019 provide reasonable assurance that the Therapy™ Cool Path™ Cardiac Ablation Catheter used in conjunction with the IBI 1500T9 RF Generator is safe and effective for the stated indications under the proposed conditions for use.

12.0 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 Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA is similar to information previously reviewed by this panel.

13.0 CDRH Decision

CDRH issued an approval order on March 16, 2007.

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

14.0 Approval Specifications

- Directions for Use: See Final Draft Labeling
- Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings and Precautions, and Potential Adverse Events in the final draft labeling.
- Post-approval Requirements and Restrictions: See Approval Order