SUMMARY of SAFETY and EFFECTIVENESS DATA

1.0 GENERAL INFORMATION

Device Generic Name: Cardiac Ablation Catheter

Device Trade Name: Stinger™ Ablation Catheter
TempLink™ Extension Cable

Name & Address of Sponsor: C.R. Bard, Inc., Electrophysiology Division
55 Technology Drive
Lowell, MA 01851

PMA Application Number: P000020

Date of Panel Recommendation: N/A

Date of Notice of Approval to the Applicant: November 29, 2000

2.0 INDICATIONS FOR USE

The Stinger™ Ablation catheter is indicated for creating focal endocardial lesions during cardiac ablation procedures to treat arrhythmias; and for cardiac electrophysiological mapping and delivering diagnostic pacing stimuli.

The TempLink™ extension cable when used in conjunction with a thermistor configured Stinger Catheter is indicated for use during cardiac ablation with set power up to 50W

3.0 CONTRAINDICATIONS

- The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus).
- The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch.
- The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

There are no known contraindications for the use of the TempLink extension cable.

4.0 WARNINGS AND PRECAUTIONS

See **WARNINGS AND PRECAUTIONS** in the professional labeling (Information for Use)

5.0 DEVICE DESCRIPTION

The device consists of the Stinger™ Ablation Catheter and the TempLink™ Extension Cable, described below. These components are used in conjunction with a compatible RF generator to deliver RF energy to endocardial structures in the treatment of cardiac arrhythmias. The specifications for a compatible RF generator are listed below.

5.1 STINGER™ Ablation catheter

Bard Electrophysiology Stinger™ Ablation catheter is a radiopaque, flexible, insulated catheter with a polymer shaft. The catheter handle has a slider mechanism which, when moved forward or back from the neutral position, results in curvature of the distal tip. The Stinger™ Ablation catheter is available in six (6) different curve configurations designated "A" through "F" as shown in Table 1 below. For ablation, the distal tip delivers up to 50W of radiofrequency (RF) energy when used in conjunction with a compatible RF generator.

The Stinger Diagnostic/Ablation catheter is a 7F quadpolar electrode catheter, configured with a 4mm distal electrode and three 1mm proximal electrodes with 2mm/5mm/2mm interelectrode spacing. The distal electrode delivers radiofrequency energy from the generator and is equipped with a thermistor-type temperature sensor to allow for physician monitoring and control of electrode temperature. The catheter has bi-directional tip curvature within a single plane. Steering of the distal tip section is accomplished by pushing or pulling a slide tab on the handle, which activates either of two pullwires to deflect the tip in the desired direction. The steerability feature is intended to provide a means of localizing and maintaining contact at the intended ablation site(s), with an adjunctive benefit of being able to straighten the catheter from a curve once the curve has been formed.

Table 1. Summary Table of Catheter Models and Features

Stinger Item No.	French Size	Poles	Spacing (mm)	Curve Type	Curve	Color
210001	7F	Quadpolar	2,5,2	A		Yellow
210002	7F	Quadpolar	2,5,2	B		Red
210003	7F	Quadpolar	2,5,2	C		Green
210004	7F	Quadpolar	2,5,2	D		Blue
210005	7F	Quadpolar	2,5,2	E		White
210006	7F	Quadpolar	2,5,2	F		Orange

5.2 TEMPLINK™ EXTENSION CABLE

The TempLink Extension cable acts as an extension cord for connection of the catheter to various EP lab devices that include commercially available ECG monitor/recorders and stimulators. The TempLink extension cable also mates with compatible RF generators via a protected pin design. The cable has a keyed connector that fits the catheter connector. The key ensures that the catheter electrodes are connected to the cable such that the identification on the cable tails corresponds to the position of the electrode (or thermistor) from the tip of the catheter (i.e., D for distal electrode, 2 for the next proximal electrode, etc. and T for thermistor lead). The cable is offered in 4 foot and 7 foot lengths.

5.3 COMPATIBLE RF GENERATOR

The Stinger™ Ablation Catheter should be used only with a legally marketed RF generator which has been shown to be safe and effective for cardiac ablation, and which is compatible with the specifications of the catheter and extension cable. Specifications for Compatible RF Generators are listed in Table 2, below.

Table 2. Specifications for Compatible RF Generators

Generator Feature	Specification
Thermometry	Thermistor
Temperature Limit, Maximum	95 °C
Modes: (must operate in all 3 modes)	Temperature Control Temperature Monitoring Power Control
Maximum Output Power	50 Watts
RF Output Frequency	450 kHz-550 kHz
Impedance Cut-off	High: 300 ohms Low: 50 ohms

6.0 ALTERNATIVE PRACTICES AND PROCEDURES

Therapeutic options for patients with arrhythmias are dependent upon the specific arrhythmia that is present. For many arrhythmias, an alternative practice is antiarrhythmic drug therapy. Depending on the type of arrhythmia, alternative practices and procedures may also include surgery, pacing therapies, or implantable cardioverter-defibrillators (ICD).

7.0 MARKETING HISTORY

The Stinger™ Ablation Catheter and TempLink™ Extension Cable have been marketed since early 1998 in European and Latin Pacific countries, and Australia and New Zealand. The Stinger catheter and TempLink cable have not been withdrawn from marketing in any country for any reason related to safety and effectiveness.

8.0 ADVERSE EVENTS

8.1 Observed Adverse Events

Adverse events that were observed during the U.S. clinical trial of the Stinger™ Ablation Catheter and TempLink™ Extension Cable are shown in Table 3 below. A total of 13 major adverse events were reported for 11 patients. These events included transient complete heart block and transient heart block, first degree AV block, tamponade from RV perforation, cardiac arrest, pericardial effusion, heart failure, CVA, atrial lead microdisplacement, acute renal failure, pneumonia, fever, and a sudden onset of severe back, chest and upper abdominal discomfort.

Table 3. Adverse Events - Major, Procedural Minor, and Deaths
Population: All Patients Enrolled (N=251)

	Number of Events	Number of Patients	Percent of Patients
Major Events	13	11/251	4.4%
Procedural Minor Events	37	29/251	11%
Patients Deaths	3	3/251	1.2%

Three (3) patients died during the study. None of the deaths were considered related to the use of the study device.

8.2 Potential Adverse Events

Adverse events (in alphabetical order) which may be associated with catheterization and ablation include, but are not limited to:

- anaphylaxis (allergic reaction) with breathing problems, drop in blood pressure and possibly death
- angina (chest discomfort)
- arrhythmia (irregular heartbeat)
- arterial/venous thrombosis (clot formation on the inside wall of the artery at the entry site)
- AV fistula (a communication between the artery and vein at the site of catheter insertion)
- back pain and/or groin pain
- cardiac perforation (hole in the lining of the heart)
- hematoma formation (bruise or bleeding into body tissue) in groin area
- hypotension (fall in blood pressure)
- infection
- myocardial infarction (heart attack)
- pericardial effusion or cardiac tamponade (collection of blood in lining of the heart)
- pneumothorax (an accumulation of air or gas in the pleural space)
- significant blood loss which may lead to blood transfusion
- skins burns (injury to the skin caused by the electrical current)
- thrombotic events including stroke and pulmonary emboli
- unintentional complete heart block requiring a pacemaker
- vessel wall or valvular trauma which may lead to surgical repair

9.0 SUMMARY OF PRECLINICAL STUDIES

Non-clinical bench testing and animal testing have been conducted to demonstrate the safety, reliability and performance of the Stinger Ablation System. The following sections summarize the results of this testing.

9.1 Non–Clinical Laboratory Studies

9.1.1 Bench Testing – Stinger Ablation Catheter: Biocompatibility

The patient contacting materials in the device include Pebax, polyethylene, stainless steel, platinum, barium sulfate, bismuth subcarbonate and epoxy**.** Finished, EtO sterilized devices were subjected to biocompatibility testing in accordance with the requirements of ISO 10993. The tests performed and the results are given in Table 4 below.

Table 4. Biocompatibility testing performed with the device.

Test	Result
CYTOTOXICITY – conducted in accordance with ISO 10993-5	MEM test extracts showed no evidence of causing cell lysis or toxicity. The negative controls, reagent controls, and positive controls performed as anticipated.
SENSITIZATION, Guinea Pig, maximization method (ISO 10993-10)	Under the conditions of the study, the SC and CSO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
IRRITATION, Acute intracutaneous reactivity study, rabbit (ISO 10993-10)	Under the conditions of the study, there was no evidence of significant irritation or toxicity from the extracts injected intracutaneously into rabbits.
TOXICITY, Acute systemic toxicity, mouse (ISO 10993-11)	Under the conditions of the study, the test article extracts would not be considered systemically toxic to the mouse at the prescribed dosage. Each test article extract met the ISO requirements.
HEMOCOMPATIBILITY 1. Hemolysis 2. Coagulation (ISO 10993-4) 3. In Vivo Thrombo-resistance (ISO 10993-4) 4. Complement Activation	 1. The negative and positive controls performed as anticipated. The test article was non-hemolytic 2. The coagulation time of the plasma after exposure to the test article was within the expected coagulation time of the plasma control. 3. After 4 hours of implantation, the test article exhibited minimal to moderate thrombus formation. Thrombus formed on the blue portion of the catheter shaft, not the distal tip. There appeared to be no changes in the hematologic and coagulation parameters. 4. The test article exhibited activation at 13,710 ng/ml. This was 10% of the normalized C3a concentration produced by the positive reference control material. The low control, human serum, positive control, and reference control materials performed as anticipated.
PYROGENICITY (ISO 10993-11)	The total rise of rabbit temperatures during the 3-hour observation period was within the acceptable USP limits. The extract was judged non-pyrogenic.

The biocompatibility of the catheter handle was evaluated separately since this component does not contact the patient or patient fluids. The sponsor performed a cytotoxicity study (the test article was judged non-cytotoxic) and a physico-chemical study to characterize the non-volatile residue, residue on ignition, heavy metals and buffering capacity of the test article.

9.1.2 Bench Testing: Electrical and Mechanical

Fourteen catheters were subjected to conditioning and testing, going from the least-destructive tests to the most destructive tests. Conditioning consisted of 1X sterilization, accelerated aging representing six months, temperature and humidity cycling (in accordance with IEC 601-1 Part I, §10.1; and IEC 68-2-30 Part 2, Figures 1 and 2a), and shipping and drop-test pre-conditioning (per NSTA Project 1A).

Table 5. Electrical and Mechanical Bench Tests

TEST DESCRIPTION (N=14 unless otherwise specified)	**METHODS**	**PASS/FAIL CRITERIA**	**RESULTS**
Radiopacity **(N=5)**	Radiographic density of images were compared to a marketed catheter (Cordis Corp.)	Radiographic density had to meet or exceed that of either a marketed catheter or of a calibration standard.	All 5 samples exceeded the image density of the marketed catheter in the proximal shaft section, but were less opaque in the distal shaft section. The distal shaft section compared favorably to a calibration standard. Electrodes were clearly visible.
Tip Cycling	Catheter subjected to 125 tip steering deflections, plus 20 cycles manual flexion of the shaft.	Visual inspection must demonstrate mechanical integrity.	All samples passed with no degradation in steering performance.
Ablation Conditioning	Specimens were subjected to 35 RF ablations with catheter tip fully deflected and submerged in 37 °C saline bath.	Visual inspection and dimensional measurements of tip to determine if swelling of the tip tubing occurred.	All samples passed with no sign of tip tubing swelling.
Tip to Tip-Stock Torque Conditioning	Specimens exposed to rotational forces of ± 45 °. Designed to simulate cleaning stresses.	Visual inspection	Subsequent electrical testing revealed no functional failures.
Seal Integrity	Exposed specimens to a pressurized soak condition, for a minimum of 15 hours.	(Performance not specifically tested)	(Performance of catheters established in subsequent tests)
Circuit Resistance and Isolation	Measured circuit resistance and circuit-to-circuit isolation.	Resistance ≤ 3.5 Ohms Isolation > 15 Mohms, which is improved from Bard's previously marketed devices	All samples passed.

TEST DESCRIPTION (N=14 unless otherwise specified)	**METHODS**	**PASS/FAIL CRITERIA**	**RESULTS**
Circuit Capacitance	Capacitance evaluated across all (14) combinations of circuits.	Capacitance ≤ 175 pF, the capacitance for another Bard device.	All samples passed.
Temperature Accuracy and Rise Time	Time	Ranges were given for the resistance specs at 30 °C, 60 °C and 95 °C. Rise time ≤ 0.8 sec.	Three catheters failed, but an explanation was given. The statistical calculations were re-run removing those values, and the remaining catheters passed.
HF Current Leakage	Catheters subjected to 24-hr saline soak. Leakage current measured through shaft while applying 140V at 500 kHz to electrodes	Leakage current < 8.17 mA/cm per AAMI HF-18, section 4.2.5.2	All catheters passed, with a worst-case reading of 4.1 mA/cm
Catheter Impedance **(N=6)**	Dynamic impedance of catheter measured while applying DC, 5 kHz, or 500 kHz voltages.	No pass-fail criteria.	Impedance and reactance measurements consistent with other products.
Catheter Buckle Test	Axial force applied to distal tip and peak force measured prior to buckling.	Buckling force compared to another marketed catheter and to peak forces required to perforate the pig ventricular apex (1.2 lbs) or maximally distend (without perforation) the r. atrial appendage (0.46 lbs)	All devices compared favorably to the marketed catheter, with about half the peak force required to buckle (0.42 lbs vs. 0.77 lbs). In addition, the peak force was well below the perforation force of the ventricular apex.
Catheter Torsion Test **(N=5)**	Count turns to electrical or mechanical failure while rotating handle with fixed tip.	No specific pass-fail criteria	The devices compared favorably to another marketed product, with an average of 6.4 turns to (mechanical) failure. No electrical failures were noted.
Tip to Shaft Tensile Test **(N=8)**	Measure the tensile force required to separate the tip tubing from the shaft tubing	Tensile strength > 5.0 lbs., based on tensile strength of tip electrode adhered to cardiac tissue of 1.5 lbs.	All devices passed, with an average tensile strength of 19.6 lbs.
Tip to Tip-stock Tensile Test (**N=8)**	Measure the tensile force required to separate the tip	Tensile strength > 2.0 lbs., with same justification as above.	All devices passed, with an average tensile strength of 17.2 lbs.

TEST DESCRIPTION (N=14 unless otherwise specified)	METHODS	PASS/FAIL CRITERIA	RESULTS
	electrode from the tip tubing		
Shaft to Handle Tensile Test **(N=13)**	Measure the force required to separate the catheter shaft from the handle.	Tensile strength > 4.0 lbs., with the same justification as above.	All devices passed, with an average tensile strength of 34.0 lbs.
Handle to Connector Tensile Test **(N=13)**	Measure the force required to separate the catheter extension tubing from the catheter handle, or from the connector.	Tensile strength > 4.0 lbs., based on the tensile strength of the LEMO connector of 2.0 lbs.	All devices passed, with an average tensile strength of 14.9 and 14.6 lbs. for the two joints respectively.

Table 6. Bench Testing of Templink Extension Cable

TEST DESCRIPTION	METHODS	PASS/FAIL CRITERIA	RESULTS
HF External Leakage Current (N=30)	Tested in compliance with IEC 601-2-2 §19.101, and HF-18 Annex C.	Leakage current < 19.2 mA/cm	The cable is capable of withstanding 150% of the output of a compatible generator with an average of 1.58 mA/cm leakage current.

9.2 Animal Testing

Animal testing was performed in compliance with Good Laboratory Practices (GLP) to fulfill the following objectives:

- To establish adequate catheter mechanical performance, particularly steering and stiffness;
- To assure temperature controlling ability using a compatible RF generator; and
- To demonstrate adequate catheter performance in ablating atrial tissue.

Six healthy dogs were used to do four chronic and two acute studies. The performance of the Stinger catheter was evaluated by creating lesions in animals and collecting data on both acute and chronic safety and effectiveness. To evaluate acute safety and effectiveness, eleven lesions, in four places, were created in the four dogs with the Stinger catheter between the coronary sinus and the AV node; between the inferior vena cava and the AV node; at the tricuspid valve annulus; and at the AV node. To evaluate chronic safety and effectiveness, the Stinger catheter was used to deliver energy to nine sites in four dogs.

There were no instances of impedance rise or coagulum adherent to the electrode as a result of energy delivery from the ablation system in any of the dogs. The Stinger catheter was able to reach all of the selected sites for ablation without difficulty, and energy was delivered with a target temperature of 65 - 70°C. AV block was successfully created in the dogs in the acute study indicating catheter efficacy for AV nodal ablation. The acute lesion dimensions were similar to those found in the published literature and to those created with another marketed catheter system.

10.0 CLINICAL INVESTIGATIONS

The Stinger™ Ablation catheter and the related accessory devices were evaluated in a clinical study with the EPT-1000 TC RF generator and another investigational RF generator, for the treatment of supraventricular tachycardias (SVT).

10.1 Study Design

The Stinger™ Ablation catheter was evaluated in a prospective, multi-center trial. Acute success was defined as the proportion of patients where treatment with the study device was able to: 1) eliminate the functioning of aberrant pathways in patients with symptomatic SVT caused by accessory pathways, 2) eliminate the functioning of aberrant pathways in patients with symptomatic SVT caused by AVNRT, 3) ablate the AV node for control of a rapid ventricular response in patients with symptomatic, drug resistant tachycardias. Chronic success (Freedom from recurrence of arrhythmia) was defined as the proportion of acute success patients, who, at a minimum of 3 months post ablation, continue to have: 1) an absence of symptoms related to the index arrhythmia; or 2) effective AV block.

10.2 Patients Studied

Patients Enrolled in Study..... 251

Patients Discontinued Prior to Study..... 4

- target arrhythmia non-inducible..... 3
- target arrhythmia non indicated..... 1

Patients Treated in Study..... 247

10.3 Demographics

Patient Demographics for the study are shown in Table 7 below. The number of arrhythmia types treated and the percentage of patients with these arrhythmias are shown in Table 8 below.

Table 7. Patient Demographics
Population: All Patients with Treatment Attempted
N=247 [Males 68% (167) / Females 32% (80)]

	N	Mean	Std. Dev	Minimum	Maximum	Median
Age (years)	247	51.3	15.9	18.0	90.0	50.0
Duration of SVT Symptoms (years)	244	13.6	13.6	0.0	69.9	9.6
Frequency of SVT Symptoms (times/year)	224	99.6	238.4	0.1	1826.3	12.0
No. of SVT Episodes (in Last 6 months)	212	28.1	76.7	0.0	600.0	6.0
No. of Hospital Visits (in Last 6 months)	247	1.1	1.3	0.0	8.0	1.0

Table 8. Number of Arrhythmia Types Treated

	Percent of Patients N=247	Number of Arrhythmias N=251
Accessory Pathway - Concealed	10%	25
Accessory Pathway - Non-concealed	10%	25
Accessory Pathway - both types	1%	3
AVNRT	66%	163
AV Node Ablation for Rate Control	14%	35

Note: 4 patients had both an Accessory Pathway and AVNRT treated.

10.4 Procedure Data

For most of the procedures (99%, 240/242 patients), energy was delivered using the constant temperature mode. Catheters were most often exchanged due to needing a different catheter curve (63%, 41/65 energy deliveries). The reason for terminating the energy delivery was usually based on the desired time interval being achieved (56%, 882/1588). Additional information on the energy delivery is shown in Table 9 below.

Table 9. Parameters of Energy Delivery

mean number of energy applications per patient	6.5 ± 6.2
mean duration per application (seconds)	43.3 ± 29.2
mean duration for all of the energy applications in a single procedure (seconds)	283.4 ± 280.2
temperature setting (°C)	61.2 ± 5.2°C
actual delivered temperature (°C)	55.7 ± 7.2°C.
mean ablation (procedure) time (minutes)	63.2 ± 62.5
mean fluoroscopy time (minutes)	24.4 ± 22.1

10.5 Acute and Chronic Effectiveness

As shown in Table 10 below, of the 247 patients treated with the Stinger™ Ablation Catheter, acute success was achieved in 230 patients (93%). There were a total of 17 acute failures of which 12 procedures were completed with a non-protocol device, no energy was delivered in 4 procedures due to RF generator malfunction, and the study device was not used in 1 patient due to the patient's tortuous anatomy.

Table 10. Success Results for Specific Arrhythmias

	Acute Success	**Freedom from Recurrence of Arrhythmia at 3 months for Patients Successfully Treated (Chronic Success)**
Accessory Pathway	88% 43/49	93% 38/41
AVNRT	95% 151/159	97% 146/150
AV node	91% 32/35	100% 31/31
>1 Type	100% 4/4	100% 4/4
Total *	93% 230/247 CI: [89%, 96%]	97% 219/226** CI: [95%, 99%]

* Exact 95% confidence intervals (CI) based on the binominal distribution

** Four (4) patients not evaluated for chronic success due to 1 death and 3 lost-to-follow-up prior to 3 months.

Antiarrhythmic Medications: For this study, a medication was considered antiarrhythmic if it was given specifically for treatment of the patient's arrhythmia. The percentage of patients receiving antiarrhythmia medications before and after the ablation are shown in Table 11 below.

Table 11. Antiarrhythmic Medications

	% of Patients Prior to Ablation	% of Patients at 3 Months
All	68% (156/230)	11% (25/226)
Accessory Pathways	53% (23/43)	5% (2/41)
AVNRT	68% (102/151)	7% (11/150)
AV Node	88% (28/32)	39% (12/31)
>1Type	5% (3/4)	0% (0/4)

10.6 Observed Adverse Events

A summary of the major and minor adverse events and patient deaths observed in this study were listed in section 8.0 above. A total of 37 minor procedural adverse events (as summarized in Table 12 below) were reported for 29 patients:

Table 12. Procedural Adverse Events
Population: All Patients Enrolled (N=251)

	Number of Occurrences
Abnormal ECG	1
Abnormal Vision	1
Application Site Reaction	1
Asthenia	1
Back Pain	1
Bundle Branch Block	1
Chest Pain	6
Dizziness	1
Ecchymosis	1
Fever	2
Injection Site Pain, Hemorrhage or Mass	8
Nausea (with or without vomiting)	3
Neck Pain	1
Pain	1
Syncope (vasovagal)	7
Ventricular Arrhythmia	1
Total:	37

11.0 SAFETY AND EFFECTIVENESS DATA FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS WITH SIMILAR RF ABLATION CATHETERS

RF ablation catheters for the treatment of cardiac arrhythmias are a mature technology. The biophysics of RF lesion creation when using conventional RF technology is also well-characterized and predictable as reported in the medical literature[1-3], especially when the lesions are created with a "conventional" RF ablation catheter. The FDA considers "conventional" RF ablation catheters to have the following characteristics:

- Create endocardial lesions
- Single 4-5 mm ablation electrode
- Temperature sensing capability
- Not irrigated or cooled
- "Steerable" (i.e., catheter has a manually-deflectable tip)

- Placed percutaneously
- Designed to deliver a maximum of 50W RF power to the endocardium

The FDA considers the Stinger™ Ablation Catheter to be a "conventional" RF ablation catheter.

There is extensive medical literature reporting the safe and effective use of conventional RF ablation catheters for treating a variety of arrhythmias in addition to those studied in the clinical trial of the Stinger™ Ablation Catheter. Table 13 show data pooled from the medical literature on three arrhythmias treated with cardiac ablation. Literature data for these arrhythmias were chosen to demonstrate the safety and effectiveness of using conventional RF catheters to create either focal or linear lesions in any of the four chambers of the heart.

Table 13: Safety and Effectiveness of RF Ablation Using Conventional RF Ablation Catheters

Arrhythmia	N	Acute Success	Chronic Success	Complications	Comments
Atrial Flutter[4,9-11,13,14,16]	1437	72 - 100%	85-100%	0 - 6%	Linear lesions across isthmus
Ventricular Tachycardia [13,14,16]	1463	66 - 85%	86%	2 - 8%	Right and left ventricles
Atrial Tachycardia [7,16]	494	91%	85%	3%	Right and left atria

American College of Cardiology/ American Heart Association Guidelines

Under the American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for Clinical Electrophysiological and Catheter Ablation Procedures,[15] RF ablation is given a Class I indication for the treatment of many tachyarrhythmias. Class I indications are defined as the preferred treatment modality by general agreement in the medical community. The ACC/AHA guidelines are widely accepted and have been adopted into current medical practice and are included in training programs for cardiac electrophysiology.

Summary of data from the medical literature

The combination of published safety and effectiveness data and the published ACC/AHA guidelines for clinical use support a broader arrhythmia indication than the specific arrhythmias treated in the clinical study of the Stinger™ Ablation catheter.

12.0 CONCLUSIONS DRAWN FROM STUDIES AND FROM DATA IN THE MEDICAL LITERATURE

The preclinical testing demonstrates that the catheter should maintain its mechanical and electrical integrity and that the patient-contacting materials should be biocompatible, under the proposed conditions of use. The animal testing established the adequate performance of the device in terms of its maneuverability and lesion creation. The data collected in the clinical study, as well as data

from the medical literature, provide reasonable assurance that the Stinger Ablation System is safe and effective for the stated indications, under the proposed conditions of use.

13.0 PANEL RECOMMENDATION

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

14.0 FDA DECISION

FDA determined that the device is reasonably safe and effective when used as indicated in the labeling. CDRH issued an approval order for the applicant's PMA, P000020, on November 29, 2000.

15.0 APPROVAL SPECIFICATIONS

Directions for Use: See Final Draft Labeling (Information for Use)

Hazards to Health from Use of the Device: See **INDICATIONS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS,** and **ADVERSE EVENTS** in the final draft labeling (Information for Use).

Post-approval Requirements and Restrictions: See Approval Order

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