SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Diagnostic ablation catheter

Device Trade Name: Helios® II Ablation Catheter

Applicant's Name and Address: Stereotaxis, Inc., 4320 Forest Park Blvd., Suite 100
St. Louis, MO 63108

Date(s) of Panel Recommendation: none

Premarket Approval Application (PMA) Number: P050029

Date of FDA Notice of Approval: October 10, 2008

Expedited: not applicable

II. INDICATIONS FOR USE

The Helios II® Ablation Catheter is indicated for use in cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, and for the creation of endocardial lesions to treat patients with supraventricular (SVT) tachycardias.

It is indicated to eliminate atrioventricular reentrant tachycardia (AVRT) in patients with overt or concealed accessory pathways, to eliminate atrioventricular nodal re-entrant tachycardia (AVNRT), and to create complete atrioventricular (AV) nodal block in patients with difficult to control ventricular response to atrial fibrillation.

The Helios II Ablation Catheter is indicated for use with the Biosense Webster Stockert 70 RF Generator via a Biosense Webster cable model C6-MR10/MSTK-S (6 foot) or C10-MR10/MSTK-S (10 foot).

The Helios II Ablation Catheter is for use only with the Stereotaxis Magnetic Navigation System (MNS) and is compatible with the Cardiodrive Catheter Advancement System (CAS).

III. CONTRAINDICATIONS

The catheter is not intended for use in the coronary vasculature, other than the coronary sinus.

Do not use the Helios II Ablation Catheter:

- in patients with active systemic infection;

- via the transseptal approach in patients with left atrial thrombosis or myxoma, or interatrial baffle or patch; or

- via the retrograde transaortic approach in patients with aortic valve replacement.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Helios II Ablation Catheter labeling.

V. DEVICE DESCRIPTION

The Helios® II Ablation Catheter is a sterile, single use, 7F, 8F catheter constructed of thermoplastic elastomer material and has one 4mm ablation electrode at the tip and one 2mm band electrode along the catheter body proximal to the tip electrode. The catheter includes a thermocouple at the tip electrode for temperature monitoring. The tube is advanced through the blood vessels until it reaches the heart either manually or by a Catheter Advancement System. The catheter is then navigated by a Magnetic Navigation System.

The catheter is sterilized using ethylene oxide and is intended for single use only.

The table below summarizes the description of the Helios® II Ablation Catheter.

Table 1 – Catheter Characteristics

Feature	Description
Useable length	125 cm
Shaft	7 French diameter, braided Pebax
Distal tip (Active) Electrode	• 8 French diameter, 4 mm in length, • Platinum-Iridium tip
Ring (Passive) Electrode	• 8 French diameter, 2 mm in length, • Platinum-Iridium
Temperature-sensing Capability	Type T thermocouple temperature sensor
Steerable	Tip deflection via magnetic navigation
RF Power	Maximum 50W
Electrical Connector	10-pin female connector at proximal end
Magnets	Neodymium, iron, and boron, cylindrical, parylene coated

The Helios® II Ablation Catheter is distinct from other conventional ablation catheters in that:

- navigation and steering of the Helios® II Ablation Catheter is accomplished via magnetic fields generated by a Stereotaxis Magnetic Navigation System [MNS] rather than manually applied rotational torque and articulation wires; and

- the distal portion of the Helios® II catheter shaft is more flexible conventional ablation catheters.

The use of magnetic navigation and steering allows the catheter tip to be deflected in any direction within three-dimensional space. The Helios II Ablation Catheter does not require the physician to manually twist or torque the shaft. Enhanced flexibility in the distal portion of the catheter shaft allows maximum deflection of the tip using a Stereotaxis MNS.

The Helios II Ablation Catheter is designed for use with the Biosense Webster Stockert 70 Radiofrequency (RF) Generator via a Biosense Webster cable model C6-MR10/MSTK-S (6 foot) or C10-MR10/MSTK-S (10 Foot) and for delivery of up to 50 Watts of RF power. The Helios® II Ablation Catheter does not include any accessories.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of supraventricular (SVTs) tachycardias. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle. Therapeutic alternatives for the treatment of supraventricular (SVTs) tachycardias include:

- anti-arrhythmic drug therapy;
- surgical ablation;
- anti-arrhythmic pacing therapies;
- catheter ablation with different approved catheters; and
- implantable cardioverter-defibrillators (ICDs).

Antiarrhythmic drugs, although effective in many patients, may be associated with significant side effects and are not curative. Surgical ablation may be curative but also associated with higher morbidity than catheter ablation.

VII. MARKETING HISTORY

The Helios® II Ablation Catheter was introduced in the European Union in April 2004. This device has not been withdrawn from the market in any country for any reason related to safety and effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- Discomfort due to insertion/removal of vascular sheaths
- Hemorrhage and/or hematoma at sheath insertion site
- Extremity weakness, swelling, and/or pain
- Discomfort and/or damage to the skin, muscles, or nerves due to remaining in a supine position for an extended period of time.
- Discomfort and/or damage to the skin, muscles, or nerves due to percutaneous access
- Nausea / vomiting
- Headache
- Dyspnea or shortness of breath
- Increased or decreased blood pressure
- Brief "black out" periods
- Feeling of chest pain, skipped beats, and/or rapid heart rate
- Damage to skin from prolonged exposure to x-rays
- Atrial Fibrillation
- Arrhythmia
- Arterial injury
- Thromboembolism
- Stroke
- Transient Ischemic Attack (TIA)
- Local/systemic infection
- Pneumothorax
- AV fistula
- Thrombophlebitis
- Pulmonary embolism
- Myocardial infarction
- Complete AV block requiring pacemaker insertion
- Myocardial perforation
- Cardiac tamponade due to perforation
- Death
- Pericardial effusion
- Arterial/venous thrombosis
- Blood loss requiring transfusion
- Hemothorax
- Valvular damage (mitral or tricuspid)
- Unintended sinus node dysfunction requiring pacemaker insertion
- Pseudoaneurysm
- Vasovagal reaction
- Allergic reaction to anesthetic agent or ionic contrast
- Pericarditis
- Renal failure due to IV contrast

For the specific adverse events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF PRECLINICAL STUDIES

A. Laboratory Studies

Biocompatibility

The Helios® II Ablation Catheter consists of the following components and corresponding materials that come into direct contact with blood:

Table 2 – Devices Materials

Part Description	Material
Tip Electrode	Platinum/Iridium
Coupler	PEEK
Ring Electrode	Platinum/Iridium
Adhesives	Loctite 4981, Dymax 204 CTH
Magnet Cover	Pebax 5533, 25% $BaSO_4$, Colorant, Stabilizers
Stem Magnet	Pebax 2533, 25% $BaSO_4$, Colorant, Stabilizers
Stem Distal	Pebax 3533, 25% $BaSO_4$, Colorant, Stabilizers
Stem Intermediate	Pebax 4033, 25% $BaSO_4$, Colorant, Stabilizers
Stem Proximal	Pebax 5533, 25% $BaSO_4$, Colorant, Stabilizers
Shaft	Pebax 6333, 25% $BaSO_4$, Colorant, Stabilizers
Strain Relief	Polyolefin

Biocompatibility testing of the patient-contacting materials of the Helios® II Ablation Catheter was performed in accordance with ANSI/AAMI/ISO 10993. The catheter is considered an externally communicating device, contacting circulating blood for a limited duration. All results indicate that the materials are biocompatible for the intended use of the device. The table below shows the biocompatibility tests performed on the Helios® II Ablation Catheter.

Table 3 – Biocompatibility Test Results

Biocompatibility Test	Test Performed	Result
Cytotoxicity	L929 MEM Elution Test	Pass - Noncytotoxic
Irritation or Intracutaneous Reactivity	Intracutaneous Injection Test	Pass - Nonirritating
Systemic Toxicity (Acute)	Systemic Injection Test	Pass - Nonreactive
Pyrogenicity	Rabbit Pyrogen Test	Pass - Nonpyrogenic

Biocompatibility Test	Test Performed	Result
	(Material Mediated)	
Sensitization	Kligman Maximization Test	Pass - Nonsensitizing
Hemocompatibility	Prothrombin Time Assay – ISO	Pass - Hemocompatible
	In Vitro Hemocompatibility Assay - ISO	Pass - Hemocompatible
	Lee and White Coagulation Test – ISO	Pass - Hemocompatible
	Direct Blood Contact	Pass - Hemocompatible

Mechanical and material performance reliability

The following table shows the mechanical and material testing performed and results to demonstrate the performance reliability of the Helios® II Ablation Catheter.

Table 4 – Mechanical Testing

Test	Description	Pass/Fail Criteria	Results
MN-874: Electrode Corrosion	Examine the corrosion resistance of the exposed metallic components to blood like components	Tip and ring electrode components of the catheter shall not show visual signs of corrosion when tested as described in Annex A of ISO 10555-1: 1995 (E).	Passed
MN-754: Radiopacity	Determine radiopacity of the compounded tubing used for the Helios II Ablation	The catheter shaft should be moderately radioopaque as compared with standard EP mapping catheters. The electrodes shall be distinguishable from the remainder of the catheter or evaluate the radiopacity using the method described in ASTM F640.	Passed
MN-870: Catheter Flexion	Evaluate mechanical and electrical functional properties after fatigue testing	The catheter must maintain electrical continuity, isolation and catheter integrity following fatigue cycling.	Passed
MN-869: Magnetic Deflection	Evaluate deflection performance of ablation	2 inches from the distal tip and the tip exposed to 0.8T at room temperature the catheter shall meet defined deflection characteristics.	Passed
MN-915-R: Bond Tensile	Ensure each bond in the design of the ablation catheter is capable of	The minimum force at break for all catheter shaft components and connections should be	Passed

Test	Description	Pass/Fail Criteria	Results
	meeting the ISO catheter tensile specification	greater than 3.4 lbs.	
MN-768: Subassembly Bond Torque	To ensure each bond in the design of the ablation catheter is capable of meeting the catheter torque specification	Each of the catheter shaft connections when subjected to a torque force must meet the following condition: Using about a 5cm test length with the bond centered in the test fixture, with one side of the bond fixed, the rotated side of the bond must meet a minimum of 5 complete rotations before breaking.	Passed
MN-873: Shaft Torque	Determine the torque characteristics of the 63D braided Pebax shaft material	For reference only, in order to characterize the torque which can be generated in the catheter, the catheter proximal shaft must be subjected to rotation at one end while the other end is fixed and the maximum torque and number of rotations must be recorded. The testing is to be performed at body temperature. The resulting data will be used to generate a plot of Torque vs angle of twist/length and approximate the product of shearing modules of elasticity and moment of inertia by Torque=(G*J)* angle of twist/length.	Passed
MN-868: Full Unit Torque	Establish the ability of the catheter design to meet the catheter minimum torque specification	With the distal tip fixed, the catheter must be able to withstand 5 full rotations of the catheter before any component of the catheter fails.	Passed
MN-904: Catheter Leak	Measure fluid leakage under internal pressure to assure fluid communication between the blood stream and the internal components of the catheter	The catheter should hold an internal pressure of 1000 mmHg (20 psig).	Passed
MN-816: Connector Separation	To ensure the connector separation force of the catheter meets specification	The connector separation force should be in the range of 1.0 lbs. – 2.7 lbs.	Passed
MN-815: Buckle Force	Measure the force required to buckle catheter tip	When restrained one inch proximal to the distal tip, the force required to buckle the	Passed

Test	Description	Pass/Fail Criteria	Results
		catheter should be less than 2.5 lbs.	
MN-429: Tip Force on Tissue	Measure the forces the catheter could place on tissue	The force produced by the electrode tip during a magnetic catheter deflection and / or translation must not exceed 0.75 lbs.	Passed
MN-770: Shaft Deflection	To determine the stiffness characteristics of the shaft material	Reference Only. The data will be used to compare the characteristics of Helios II Ablation Catheter shaft materials to the MC1 Mapping Catheter.	Passed
MN-875: System Compatibility	Evaluate the 10 pin version of the ablation catheter compatibility with the junction cable and ablation generator	System generator, cables and catheters are compatible.	Passed

Electrical performance reliability

The following tests were performed to demonstrate the electrical performance of the Helios® II Ablation Catheters.

Table 5 – Electrical Testing

Test	Description	Pass/Fail Criteria	Results
MN-866: High Frequency Leakage Current	Evaluate current from the catheter at 500 KHz	The high frequency leakage current shall not exceed 3.6d mA per cm of catheter length (where d is the smallest outer dimension of the catheter in mm. The applied voltage shall be >173.2 V p-p (equivalent to 1.5x50W=75W) at the manufacturers specified frequency per AAMI HF-18 section 4.2.5.2, tested per section 5.2.5.2.	Passed
MN-867: Conductor to Conductor Coupling	Measure the power leakage from the proximal electrode compared to distal ablation electrode	The catheter power leakage from the tip electrode to the ring electrode must be less than 5% of the input power .05*75W=3.75W). 75W represents maximum power of the Helios II Ablation Catheter and any resulting leakage within the specified limits due to coupling will not result in power levels which are clinically	Passed

Test	Description	Pass/Fail Criteria	Results
		significant. The applied voltage shall be >173.2 Vp-p (equivalent to 1.5x50W=75W).	
MN-817: Catheter Dielectric	Evaluate the dielectric capability of the catheter and cables at 1.5x normal operating voltage at 500 KHz	The catheters must withstand a low frequency test voltage of 3000 Vrms at 60 Hz for 5 minutes.	Passed
MN-932: Temperature Response	Evaluate the effect of a 0.1 Tesla magnetic field on the temperature response time of the Helios II catheter's distal temperature sensor	The catheter shall respond to 90% of the stepped temperature change in less than 5 seconds.	Passed
MN-704: Ablation Reliability	Evaluate ability of catheter to create lesions after being subjected to multiple deflection and ablation cycles	The catheters must not show visual signs of deterioration, the continuity of all circuit paths must be maintained, and the band electrode should remain electrically isolated from the tip electrode specification.	Passed
MN-818: Catheter Electrical Characteristics	Evaluate the electrical properties of the catheter to include of resistance, electrode isolation and impedance	Electrical Resistance: The resistance in each electrode pathway shall be no more than 10 ohms. Electrical Isolation: The continuity pathways of each electrode on the catheter shall be isolated (Resistance > 1Mohm). Electrical Impedance: The catheter impedance at these two frequencies (500kHz & 5kHz) should not differ from one another by more than 18Ω for every combination of electrical conductance pathway. *Specification:* The direct current resistance and the impedance at 5,000 Hz should not differ by more than 5 ohms.	Passed
MN-435: Magnetic Pick-Up Noise	Measure unwanted voltage noise that the catheter can pick up from the environment	Magnetic pick-up voltages must be less than 40 mV when tested per MNO-017.	Passed

Test	Description	Pass/Fail Criteria	Results
MN-931: Temperature Accuracy	Evaluate the effect of a 0.1 Tesla magnetic field on the temperature accuracy performance of a Helios II Ablation Catheter	The catheter must measure the temperature of surrounding the tip electrode to within 3°C in the temperature range of 30°C-90°C.	Passed

B. Animal Studies

A canine navigation study was conducted to evaluate the performance of the Helios® II Ablation Catheter. The study was designed to assess the safety and efficacy of the catheter to navigate within the heart chambers to locations on the endocardial surface, for the purpose of ablating heart tissue. This study was designed to evaluate the ability of the catheter design to:

- Navigate to desired locations with and without the use of the Cardiodrive® Catheter Advancement System (CAS; the CAS is not a subject of this PMA application. It was cleared under K071029 for automatically advancing and retracting only compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis Magnetic Navigation System (MNS).),
- Create clinically acceptable lesions at all ablation points, and
- Have acceptable electrograms and pacing thresholds at every site (within an acceptable noise range).

The Helios® II catheter was able to navigate to all the desired locations with and without CAS. Locations included 10 sites widely spread on both sides of the heart in order to demonstrate the catheter's ability to navigate to locations in conjunction with a Stereotaxis MNS. The catheter created clinically acceptable lesions at all ablation points, and it had acceptable electrograms and pacing thresholds at every site. All electrograms recorded with and without the use of the CAS are within the acceptable noise range.

X. SUMMARY OF PRIMARY CLINICAL STUDY

Section X discusses the primary clinical study performed to support the application. For a summary of additional supporting clinical data, please refer to Section XI.

A total of three clinical trials were conducted under two IDEs for evaluation of Helios II in the treatment of SVT. The table below provides a brief description of each clinical trial to clarify the purpose and role of each study as it relates to P050029.

Table 6

IDE	Study Name	Purpose	Description
G020129	ATTRAC	Assess the safety and efficacy of the Helios II catheter in the treatment of AVNRT, AVRT and for the creation of CHB for patients with atrial fibrillation and a rapid ventricular response.	This trial is the pivotal study in support of P050029.
	ATTRAC II	Assess the safety and efficacy of remote advancement of a magnetic ablation catheter in the treatment of AVNRT, AVRT and for the creation of CHB for patients with atrial fibrillation and a rapid ventricular response.	The Cardiodrive was first cleared for use with mapping catheters in K021802. This trial was performed as the primary support of an indication change to include magnetic ablation catheters (K071029). Enrollment began after the completion of the ATTRAC study in March 2005 and was completed in June 2006. At the time the study was initiated, there were no approved magnetic catheters. The study, therefore, involved two investigational devices: the Helios II catheter and the Cardiodrive.
G040124	Heart	The goal of this clinical study was to compare the resulting fluoroscopy time when using Cardiodrive®-assisted magnetic catheter manipulation versus manual manipulation of a conventional cardiac ablation catheter.	Enrollment was initiated in January 2005 and was closed in March 2006. At the time the study was initiated, there were no approved magnetic catheters. The study, therefore, involved two investigational devices: the Helios II catheter and the Cardiodrive.

Data from G020129 served as the primary basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

The principal study in support of the Helios II ablation catheter was the ATTRAC study. The database for this PMA/PMA supplement reflected data collected through March 10, 2005 and included 210 subjects. There were 6 investigational sites.

The study was a prospective, non-randomized, unblinded, multicenter clinical trial. The study results were compared against pre-specified performance goals to evaluate device safety and effectiveness for acute success, chronic success, acute heart injury and 7-day major complications. The performance goals used were: acute success ≥96.9%, chronic success ≥93%, acute heart injury < 1.3% and 7-day major complication rate < 2.0%. The performance goals were pre-specified in the study protocol.

1. Clinical Inclusion and Exclusion Criteria
   Enrollment in the ATTRAC study was limited to patients who met the following inclusion criteria:

   - Age 18 years old or older
   - At least one documented episode of tachyarrhythmia within the 12 months prior to enrollment
   - Women without child-bearing potential or women with a negative pregnancy test
   - MRI Compatible - Able to be safely exposed to magnetic fields, such as MRI
   - Provide signed informed consent

   Patients were not permitted to enroll in the ATTRAC study if they met any of the following exclusion criteria:

   - MRI incompatible (PPM, ICD, neuro-stimulators, aneurysm clips, cochlear implants, any other institution contraindications)
   - Unable to remain supine
   - Unable to be in confined spaces
   - Concurrent investigational studies
   - Pregnancy
   - Patient weight exceeds table weight limit
   - MI within 6 weeks prior to enrollment
   - EP ablation within 6 weeks prior to enrollment
   - Cardiac surgery within the 8 weeks prior to enrollment
   - Intra-cardiac thrombus within 12 weeks prior to enrollment
   - Life expectancy less than 12 months
   - Current unstable angina
   - Significant medical problem that, in the opinion of the investigator, would preclude enrollment in the study
   - Acute illness/active systemic infection

- Inaccessible for follow-up through the 90 days required
- Latex allergy and institution is unable to provide a latex-free environment

2. Follow-up Schedule
   All subjects were scheduled to return for two follow-up examinations between 7 and 14 days and one at 90 days postoperatively.

   Preoperatively, the data obtained on each patient included:

   • Patient Demographics
   • Medical history
   • Antiarrhythmic Drug Use
   • Echocardiogram
   • Electrocardiogram
   • Cardiac Arrhythmic Symptoms
   • Preliminary Arrhythmic Diagnosis

   Postoperatively, the objective parameters measured during the study included echocardiogram obtained within 36 hours of the procedure for the comparison of cardiac function to the pre-operative study, as well as to identify the occurrence of acute cardiac injury. Additionally, if a patient's symptoms were suggestive of a recurrent arrhythmia, per the physician's evaluation, an event recorder was used to obtain event recordings at the time(s) of onset and termination of the symptoms. Adverse events and complications were recorded at all visits.

3. Clinical Endpoints

   With regards to safety, the primary safety endpoint was acute safety defined as the incidence of acute injury to the heart based on a post-procedure echocardiogram. The secondary safety endpoint was the rate of major complications considered to be related to the investigational device or procedure during the first 7 days compared to the protocol-specified performance goals.

   With regards to effectiveness, the primary effectiveness endpoint was acute procedural success defined as the elimination of accessory pathway conduction in subjects with atrio-ventricular reentrant tachycardia, elimination of inducibility of atrio-ventricular nodal reentrant tachycardia (AVNRT) in subjects with atrio-ventricular nodal reentrant tachycardia, or the creation of complete heart block in subjects who require AV node ablation. The secondary effectiveness endpoint was Chronic success defined as the absence of recurrence of the arrhythmia (pre-excitation or AVRT in patients with an accessory ablation, AVNRT in the case of patients who undergo AV nodal "slow" pathway ablation, or AV nodal conduction in the case of patients who have had AV nodal ablation) over 90 calendar day period post-treatment.

The analysis of acute effectiveness was based on acute procedural success on a per patient basis (defined as the elimination of accessory pathway conduction in subjects with atrio-ventricular reentrant tachycardia, elimination of inducibility of atrio-ventricular nodal reentrant tachycardia in subjects with atrio-ventricular nodal reentrant tachycardia, or the creation of complete heart block in subjects who require AV node ablation).

The analysis of chronic effectiveness was based on the absence of recurrence of the arrhythmia (pre-excitation or AV reentrant tachycardia in patients with an accessory pathway ablation, AV nodal reentrant tachycardia in the case of patients who undergo AV nodal "slow" pathway ablation, or AV nodal conduction in the case of patients who have had AV nodal ablation) over a 90 calendar day period post-treatment.

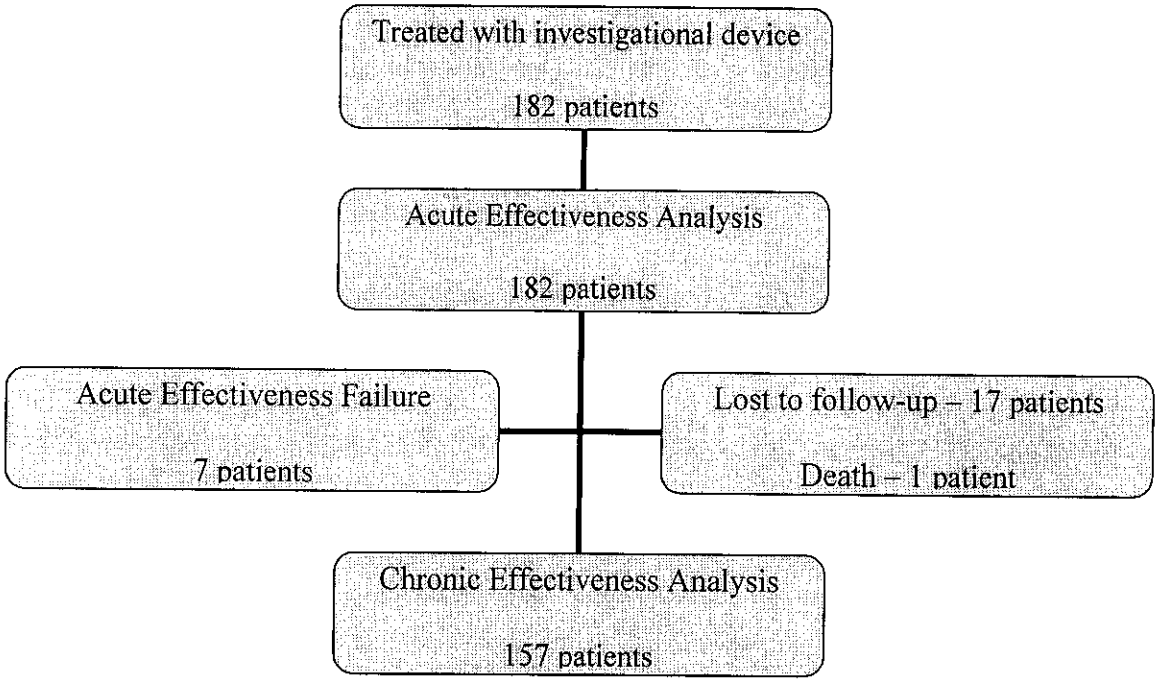
Major complications were defined as device and procedure-related major complications occurring within 7 days of the ablation procedure.

B. Accountability of PMA Cohort

At the time of database lock, of 210 subjects enrolled in PMA study, 182 subjects are available for analysis at the completion of the study, the 3 month post-operative visit *(final visit evaluated for safety and effectiveness as the basis for the PMA submission).*

Table 7: Subject Accountability

Disposition	**Total #**	
Subjects enrolled		210
Subjects not treated with the investigational catheter:	28	-28
Excluded: did not meet study inclusion criteria; catheter was not inserted	14	
Discontinued: catheter was inserted but required study arrhythmia could not be induced	11	
Discontinued: equipment failure not related to the investigational devices	3	
Subjects ablated with a Helios® Catheter:		182
Helios® I Catheter	19	
Helios® II Catheter	161	
Helios® I & II Catheters	2	



Initially, Stereotaxis intended to seek marketing approval from FDA for the original Helios® I Ablation Catheter. In support of these efforts an IDE Clinical Study Application was submitted to FDA and approved as G020129.

Early in the study, a re-design of the distal tip of the Helios I was initiated so the catheter could reach more challenging sites. The redesigned distal tip incorporated additional magnets and the catheter was renamed the Helios® II Ablation Catheter and was introduced into the IDE Clinical trial under Supplement 5. Only 21 patients received treatment with the Helios® I catheter model. The clinical results for both catheter models (Helios I and Helios II) are presented in the Clinical Study report. The outcomes when stratified based on catheter had no discernable differences. Therefore, the study results for Helios I and II were considered poolable.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a supraventricular (SVT) tachycardia ablation study performed in the US.

Table 8: Demographics

Characteristic	**Total**	
Gender	**n**	**%**
Male	73	34.8%
Female	137	65.2%
Age (yrs)	**Value**	
Mean + std dev	48.5 + 17.0	
Min	18.1	
Max	82.4	

Subjects treated by arrhythmias type	n	%
Accessory Pathway	41	19.5%
AVNRT	87	41.4%
AV Node Ablation	18	8.6%
SVT not otherwise specified	64	30.5%

D. Safety and Effectiveness Results

1. Safety Results

The analysis of acute safety was the incidence of peri-procedural acute heart injury (based on a comparison of pre- and post-procedure echocardiograms) for all patients that underwent treatment with the investigational ablation catheter and had echocardiograms performed. This resulted in a cohort of 177 patients/procedures, available for the acute evaluation (5 of the 182 patients treated with the investigational ablation catheter did not have post-procedure echocardiograms). The key safety outcomes for this analysis are presented below.

Table 9 - Echocardiographic Evidence of Acute Heart Injury

Number of Patients	Description of Adverse Event
1	New focal wall motion abnormality
1	Change in LVEF from 60% to 45-50%

Two (2) patients out of 177 (1.1%) who received a post-ablation echocardiogram in the ATTRAC Study reported acute heart injury.

The analysis of long-term safety was the incidence of device or procedure-related major complications within 7 days of the ablation procedure. The analysis included all 182 patients that underwent ablation with the study device. The 7-day device or procedure-related major complications are presented below.

Table 10 - 7-Day Device or Procedure-related Major Adverse Events

# of Events	Description
1	Linear inferior vena cava thrombus
1	Groggy (prolonged hospitalization)
1	Linear inferior vena cava clot extending into the right atrium
1	Chest soreness pain
1	Right groin pseudoaneurysm

The long-term safety results showed 5 of 182 (2.7%) patients reporting major device and procedure-related complications within 7 days of ablation.

The prolonged recovery from sedation and the pseudoaneurysm were likely related only to the ablation procedure. The presence of thrombus (IVC only in 1

instance, IVC/cardiac in 1 instance) and the development of chest soreness pain compatible with pericarditis were procedure-related and possibly device-related, as well.

A total of twenty (20) major adverse events occurred in 17 subjects of which 8 events were within 7 days of the investigational procedure, and 5 of which were identified as device and/or procedure-related (discussed above).

The 20 events include: 1 Death secondary to respiratory failure, 5 instances of COPD/Respiratory Complications, 2 instances of Cardiac Pain, 2 instances of Shortness of Breath/Dyspnea, 2 instances of Intra-cardiac Thrombus, 2 instances of Allergic Reactions, 1 instance of Fatigue/Weakness, 1 instance of Hypotension, 1 instance of Carcinoma, 1 instance of Hematoma/Vascular Complication, 1 instance of Infection (Pneumonia), and 1 instance of chronic heart failure (CHF). Fourteen (14) of the 20 events required hospitalization or resulted in prolongation of hospitalization due to Cardiac Pain, Fatigue/Weakness, Shortness of Breath/Dyspnea, Hematoma/Vascular Complication, Infection (Pneumonia), CHF, COPD/Respiratory Complications, and Allergic Reaction. One (1) death (Respiratory Failure) was observed 36 days following successful ablation in a subject with a history of COPD.

Adverse effects that occurred in the PMA clinical study:
The following table summarizes the occurrence of all adverse events reported during the ATTRAC Study. A total of 258 adverse events occurred in 117 patients.

Table 11: All Reported Adverse Events

Adverse Event	Number of Patients Experiencing	% of Patients Experiencing
Death	1	0.5%
Vascular complications	13	7.1%
Intra-cardiac thrombus	6	3.3%
Pre-syncope/syncope	8	4.4%
Bleeding	14	7.7%
Infection	8	4.4%
CHF	2	1.1%
Arrhythmia/palpitations	17	9.3%
SOB/dyspnea/wheezing	8	4.4%
Pain (cardiac)	12	6.6%
Pain (non-cardiac)	75	41%
Hypertension	3	1.6%
Hypotension	8	4.4%
Pericardial effusion	3	1.6%
Nausea/vomiting	14	7.7
Carcinoma	2	1.1%
COPD/respiratory	5	2.8%

Adverse Event	Number of Patients Experiencing	% of Patients Experiencing
complications		
Paresthesias	1	0.5%
Edema	4	2.2%
Allergic reactions	1	0.5%
Anxiety	2	1.1%
Hernia	1	0.5%
Fatigue/weakness	5	2.8%
Fracture/sprain	1	0.5%

No adverse events led to design modifications during the clinical trial.

The frequency of adverse events raised the possibility that use of the device resulted in unexpected adverse device effects. The rate and nature of the adverse events (in particular the events related to shortness of breath/respiratory complications) were compared to expected rates; it was concluded that the frequency of such events was in line with expected rates. Therefore, it is concluded that the reported adverse event rates are acceptable when considered in the context of the risk-benefit of the device.

One patient died during the ATTRAC study. The death was not related to either the procedure or the investigational catheter.

2. Effectiveness Results

The analysis of acute effectiveness was based on acute procedural success (defined as the elimination of accessory pathway conduction in subjects with atrio-ventricular reentrant tachycardia, elimination of inducibility of atrio-ventricular nodal reentrant tachycardia in subjects with atrio-ventricular nodal reentrant tachycardia, or the creation of complete heart block in subjects who require AV node ablation). The evaluable cohort included all 182 patients that underwent treatment with the investigational catheter. Key effectiveness outcomes are presented in tables 12 and 13.

Table 12: Acute Effectiveness (by Arrhythmia and Total)

	Total Patients	Success	Rate	95% LCB
AP	44	41	93.2 %	81.3 %
AVNRT	118	116	98.3 %	94.0 %
AVN ablation	18	17	94.4 %	72.7 %

Unknown (04-001)	1	0	0 %	
AVNRT and AP	1	1	100%	
Total	182	175	96.2 %	92.2 %

Overall, the device was acutely successful in 96.2% (95% LCB 92.2%) of the cases. While the point estimate did not meet the protocol-specified performance goal of > 96.9%, the acute effectiveness results demonstrate an acceptable level of successful treatment of the targeted supraventricular tachycardias.

The analysis of chronic effectiveness was based on the absence of recurrence of the arrhythmia (pre-excitation or AV reentrant tachycardia in patients with an accessory pathway ablation, AV nodal reentrant tachycardia in the case of patients who undergo AV nodal "slow" pathway ablation, or AV nodal conduction in the case of patients who have had AV nodal ablation) over a 90 calendar day period post-treatment. The evaluable cohort included 147 patients (35 patients were excluded as follows: 17 patients were lost to follow-up, 10 patients had less than the protocol minimum duration of follow-up, 1 patient died and there were 7 acute procedural failures).

Table 13: Chronic Effectiveness (by Arrhythmia and Total)

	Total Patients	Success	Rate	95% LCB
AP	34	33	97.1 %	84.7 %
AVNRT	97	96	99.0 %	94.4 %
AVN ablation	15	15	100 %	78.2 %
AVNRT and AP	1	1	100%	2.5%
Total	147	145	98.6 %	95.2 %

Overall, the device demonstrated chronic success in 98.6% (95% LCB 95.2%) of the evaluable cases. This result exceeded the protocol-specified performance goal

of >93%. The chronic effectiveness results demonstrate an acceptable level of successful treatment of the targeted supraventricular tachycardias.

3. Subgroup Analyses
The following preoperative characteristics were evaluated for potential association with outcomes: ablation catheter type employed (Helios I vs. Helios II), investigational site, gender, and continuation of anti-arrhythmic medication. There was no clear evidence that effectiveness outcomes varied based on any of the subgroups analyzed.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Two additional studies were performed that used the Helios II ablation catheter.

The ATTRAC II study was a single-arm trial designed to assess the Helios II ablation catheter in combination with the Catheter Advancement System for the treatment of patients with supraventricular tachycardia. Relevant endpoints for the ATTRAC II study were similar to the ATTRAC study. Eighty-nine (89) subjects were enrolled at 6 sites, and 75 were treated with the ablation catheter. Only 54 subjects were included in the chronic effectiveness analysis due to study exits (patients lost to follow-up and those that withdrew consent). One patient out of 69 (1.4%) who received a post-ablation echocardiogram in the ATTRAC II Study reported acute heart injury. There was one of 80 (1.3%) patients that had a device and/or procedure related major adverse event within 7 days and it consisted of cardiac perforation/tamponade. The relevant outcomes are summarized below.

Table 14: Summary of the ATTRAC II Study Results

Study Endpoint	Performance Goal	Observed	
		Point Estimate	95% Confidence Boundary
Acute effectiveness	> 96.9%	(71/75) 94.7%	86.9%
Chronic Effectiveness	> 93%	(51/54) 94.4%	84.6%
Acute Safety: • Ablation of the target site(s) without inflicting new, acute heart injury.	<1.3%	(1/69) 1.4%	7.8%
Long-Term Safety: • No excessive number of major adverse events within 7 calendar days of the ablation.	< 2.0 %	(1/80) 1.3%	6.8%

The HEART study was also designed to assess the Helios II ablation catheter in combination with the Catheter Advancement System for the treatment of patients with supraventricular tachycardia. It was a randomized trial, comparing the Helios II ablation catheter with the Catheter Advancement System to ablation using conventional ablation catheters in order to compare fluoroscopy times. However, endpoints for the HEART

study also included the major endpoints of the ATTRAC study. One hundred forty-four (144) subjects were enrolled and 129 were randomized to treatment with the Helios II ablation catheter. Eight (8) patients randomized to the Helios II ablation arm did not have a protocol-approved arrhythmia identified; therefore, the acute effectiveness cohort consisted of 121 patients. Thirty-four (34) patients treated with the Helios II ablation catheter were not included in the chronic effectiveness analysis (acute effectiveness failures, lost to follow-up or inadequate follow-up duration), leaving 87 patients in the chronic effectiveness cohort. The relevant outcomes are summarized below.

Table 15: Summary of the HEART Study Results

Study Endpoint	Helios II	Conventional Group
Acute effectiveness	(108/121) 89.3%	(13/15) 86.7%
Chronic Effectiveness	(82/87) 94.3%	(7/8) 87.5%
7-day Device & Procedure-related Complications	(7/129) 5.4%	(1/15) 6.7%

Taken together, the results of the ATTRAC II study and the HEART contribute to a determination of the reasonable assurance of safety and effectiveness of the Helios II ablation catheter for the treatment of patients with supraventricular tachycardia.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

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 Cardiovascular Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety Conclusions

The adverse effects of the device are based on data collected in a clinical study conducted to support PMA approval as described above.

Two (2) patients out of 177 (1.1%) who received a post-ablation echocardiogram in the ATTRAC Study reported acute heart injury. The long-term safety results showed 5 of 182 (2.7%) patients reporting major device and procedure-related complications within 7 days of ablation. These results are summarized in the table below.

Table 16: Summary of ATTRAC study safety results

Helios II Safety Results	Rate	95% UCB
Acute Safety: • Incidence of new, acute heart injury.	1.1%	4.0%

• Success rate defined as <1.3%		
Long-Term Safety: • Incidence of device and procedure-related major complications within 7 calendar days of the ablation. • Success rate defined as <2.0%	2.7%	6.3%

UCB = Upper Confidence Boundary

The new, acute heart injury events consisted of one each of a new, focal wall motion abnormality and a decrease in LVEF of 10-15% (comparing pre- and post-ablation echocardiograms). Both events suggest myocardial damage resulting from the ablation procedure. The incidence of new, acute heart injury was 1.1% (95% UCB 4.0%) which met the pre-specified performance goal of < 1.3%.

The 7-day device and procedure-related major complications consisted of new intravascular/intracardiac thrombus (2), chest pain/possible pericarditis (1), a pseudoaneurysm (1), and prolonged recovery from sedation (1). The incidence of 7-day device and procedure-related major complications was 2.7% (95% UCB 6.3%) which did not meet the pre-specified performance goal of < 2%. However, the nature of the events does not indicate undo risk, and when the incidence is interpreted in the context of expected adverse events rates and of the effectiveness results, the safety profile is acceptable.

B. Effectiveness Conclusions

Table 17: Summary of ATTRAC study effectiveness results

	ATTRAC	
Helios II Ablation Results	**Success Rate**	**95% LCB**
Acute success: • Successful ablation of the target sites • Success rate defined as >96.9%	96.2%	92.2%
Chronic success: • Absence of recurrence of the arrhythmia over 3 months • Success rate defined as >93%	98.6%	95.2%

The acute effectiveness of the Helios II ablation catheter (defined as the elimination of accessory pathway conduction in subjects with atrio-ventricular reentrant tachycardia, elimination of inducibility of atrio-ventricular nodal reentrant tachycardia in subjects with atrio-ventricular nodal reentrant tachycardia, or the creation of complete heart block in subjects who require AV node ablation) is a clinically relevant endpoint. The study found the acute effectiveness to be 96.2% (95% LCB 92.2%) which does not meet the pre-specified performance goal of >96.9%. However, the Helios II ablation did demonstrate substantial effectiveness for the treatment of the target

supraventricular arrhythmias, and when interpreted in the context of expected acute effectiveness success rates, the acute effectiveness profile is acceptable.

The chronic effectiveness of the Helios II ablation catheter was based on the absence of recurrence of the arrhythmia (pre-excitation or AV reentrant tachycardia in patients with an accessory pathway ablation, AV nodal reentrant tachycardia in the case of patients who undergo AV nodal "slow" pathway ablation, or AV nodal conduction in the case of patients who have had AV nodal ablation) over a 90 calendar day period post-treatment; this is a clinically relevant endpoint. The study found the chronic effectiveness to be 98.6% (95% LCB 95.2%) which met the pre-specified performance goal of > 93%.

C. **Overall Conclusions**

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

Preclinical testing demonstrates that the Helios II ablation catheter should maintain mechanical and electrical integrity and materials which contact patients should be biocompatible under the proposed conditions for use. Bench testing has established an acceptable degree of energy delivery accuracy and control.

Clinical data submitted under P050029 demonstrated that the Helios II ablation catheter is effective with an acceptable rate of complications for the stated indications under the proposed conditions for use.

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.

XIV. CDRH DECISION

CDRH issued an approval order on October 10, 2008.

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

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.