

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Diagnostic/Ablation Catheter and accessories

Device Trade Names: NaviStar™ DS 8 mm Deflectable Diagnostic/Ablation Catheter

Celsius™ DS 8 mm Deflectable Diagnostic/Ablation Catheter

Stockert 70 RF Generator (model S7001 with software version 001/033)

Catheter Interface Cables (models D-1195 and D-1170)

Applicant's Name and Address: Biosense Webster Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P010068

Date of Notice of Approval to Applicant: September 27, 2002

Device and Accessory Model Numbers:

Family Name	Model Number	
NaviStar™ DS	NS7TC-B8L-174-HS NS7TC-D8L-174-HS NS7TC-F8L-174-HS NS7TC-L8L-174-HS	NS7TC-C8L-174-HS NS7TC-E8L-174-HS NS7TC-J8L-174-HS
Celsius™ DS	D7TC-B8L-162-RT D7TC-D8L-162-RT D7TC-F8L-162-RT D7TC-L8L-162-RT	D7TC-C8L-162-RT D7TC-E8L-162-RT D7TC-J8L-162-RT
Stockert 70 RF Generator	S7001, with software version 001/033	
Catheter interface cables	D-1195: D-1170:	C5-MH/DTCMH-S C6-MR10/MSTKDTC-S C10-MR10/MSTKDTC-S

Explanation of model numbers:

For the NaviStar™ DS catheters, the letter located after the "NS7TC-" in the model number signifies the type of curve for the catheter. For example, the NS7TC-B8L-174-HS model has curve type B. Available curve types are B, C, D, E, F, J and L, each being determined by the angle between the tip and shaft of the catheter, and by the radius of the curve. Similarly, for the Celsius™ DS catheter, the letter located after the "D7TC-" in the model number signifies the type of curve for the catheter.

For the catheter interface cables, the D-1195: C5-MH/DTCMH-S catheter interface cable connects the NaviStar™ DS catheter to the patient interface unit, which is in turn connected to the Stockert 70. The D-1170: C6-MR10/MSTKDTC-S and D-1170: C10-MR10/MSTKDTC-S catheter interface cables connect the Celsius™ DS catheter to the Stockert 70 generator directly. The C6-XX catheter interface cable is 6 feet long while the C10-XX cable is 10 feet long.

Related Premarket Applications

The NaviStar™ DS catheter is derived from the NaviStar™ catheter approved under P990025, and the Celsius™ DS catheter is derived from the Celsius™ catheter approved

under P950005. The major differences are the length of the tip electrode in the present DS catheter (8 mm compared to 4 mm in the previous devices) and the use of an additional temperature sensor in the DS catheters. Further, a prior version of the Stockert 70 RF generator was approved under P990071. Relevant design specifications were maximum power output of 50 W and use for single temperature sensor only. These data are incorporated by reference in the present PMA. For more information on the data which supported each application, please refer to the summaries of safety and effectiveness data available on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written request for this information can also be made to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 under Docket # 98M-0678 (P950005), Docket # 00M-1388 (P990025), and Docket # 03M-0045 (P990071).

II. INDICATIONS FOR USE

The NaviStar™ DS and Celsius™ DS catheters and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulation and recording), and when used with the Stockert 70 (model S7001 with software version 001/033) for the treatment of Type I atrial flutter in patients age 18 or older.

The NaviStar™ DS catheter provides location information when used with the Carto EP Navigation System.

III. CONTRAINDICATIONS

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma; and
- via the retrograde approach in patients with aortic valve replacement.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the NaviStar™ DS Diagnostic/Ablation Catheter instructions for use, the Celsius™ DS Diagnostic/Ablation Catheter instructions for use, and the Stockert 70 Radiofrequency Generator User Manual.

V. DEVICE DESCRIPTION

With reference to the model numbers indicated in the above table on Device and Accessory Model Numbers, the device components which are the subject of the PMA are the following:

- A. NaviStar™ DS and Celsius™ DS Diagnostic/Ablation Catheters;
- B. Stockert 70 RF generator; and
- C. catheter interface cables.

For catheter ablation procedures, the device components require the use of the grounding pad (dispersive pad) previously approved under P990071.

For additional aid in navigation the NaviStar™ DS catheter requires the use of the following legally marketed devices:

- RefStar reference catheters -- originally cleared under K954390; and
- Carto EP Navigation System -- originally cleared under K954395 and other premarket notifications.

Description

A. NaviStar™ DS and Celsius™ DS Diagnostic/Ablation Catheters

The NaviStar™ and Celsius™ Diagnostic/Ablation DS catheters (hereinafter referred to as "DS catheter" unless otherwise specified) are two families of steerable, multi-electrode catheters with a deflectable tip.

The DS catheter outer diameter is 7 French (Fr) with a usable length of 115±3 cm. The deflectable tip of the DS catheter has one 8 mm platinum/iridium tip electrode and three platinum/iridium ring electrodes used for pacing and recording ECG signals. The spacing is 0.5-1.0 mm between the tip and 1st ring electrode, 4.5-5.5 mm between the 1st and 2nd ring electrodes, and 2-2.5 mm between the 2nd and 3rd ring electrodes. All electrodes may be used for recording and pacing, but only the tip electrode can be used to deliver RF energy.

The DS catheter is equipped with two thermocouple temperature sensors embedded in the tip electrode that provide signals to the Stockert generator, which displays the higher of the two electrode temperatures and controls RF energy delivery during cardiac ablation.

The DS catheter is designed to deliver up to seventy (70) one-minute applications of RF energy. It is provided sterile and for single patient use only.

A.1 Difference between NaviStar™ DS and Celsius™ DS Catheters

Unlike the Celsius™ DS catheter, the NaviStar™ DS catheter includes a location sensor, which consists of three orthogonally arranged sensor coils. The catheter is used with the Carto EP Navigation System to generate catheter locational and orientation information by interacting with a small alternating current (AC) magnetic field propagating from the location pad placed under the patient table.

B. Stockert 70 RF Generator, with Software Version 001/033

A prior version of the Stockert 70 RF generator was previously approved under P990071 for delivering up to 50 W of RF power. In the present PMA, the Stockert 70 generator (with software version 001/033) was modified (a) to deliver up to 70 W of RF power and (b) to read two thermocouples simultaneously, while choosing the higher of the two temperature readings. To sense two thermocouples simultaneously, the generator's temperature tolerance was increased to ± 5 °C.

The Stockert 70 can detect the specific catheter to which it is connected. It will deliver up to 70 W of power only if it detects that it is connected to the NaviStar™ DS or the Celsius™ DS catheter. Otherwise, it will deliver only up to 50 W.

C. Catheter Interface Cables

The Catheter Interface Cables (models D-1195 and D-1170) in this PMA are similar to other marketed cables except that each cable can carry two thermocouple signals, in addition to other signals, from the DS catheter to the Stockert 70 generator. The D-1195 cable connects the NaviStar™ DS catheter to the patient interface unit in the Carto system, and the D-1170 cables connect the Celsius™ DS catheter to the Stockert 70 generator directly. These reusable cables are supplied sterile by the sponsor

VI. ALTERNATIVE PRACTICES OR PROCEDURES

Alternative therapy for atrial flutter includes direct surgical ablation, use of drugs for arrhythmia control, and antiarrhythmia pacing.

VII. MARKETING HISTORY

The NaviStar™ DS and Celsius™ DS Diagnostic/Ablation Catheters and accessories are available for sale in Canada, Europe, South America and the Pacific Rim countries.

The Stockert 70 (with software version 001/033) has not been marketed in other countries. Other Stockert generator models that allow RF outputs of 70 watts or greater for multiple catheters have been marketed in Europe, Asia, South America, Canada, the Middle East, and South Africa.

There are no countries from which the NaviStar™ DS and Celsius™ DS catheter, Stockert RF generator, or the related accessory devices have been withdrawn from marketing for any reason related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential Adverse Events associated with cardiac ablation for treatment of atrial flutter include the following:

- | | |
|--|---|
| <ul style="list-style-type: none">• Air embolism• Anemia• Atypical flutter• AV fistula• Cardiac perforation/tamponade• Cardiac thromboembolism• Cerebrovascular accident (CVA)• Chest pain/discomfort• Complete heart block• Congestive heart failure• Death• Endocarditis• Exacerbation of pre-existing atrial fibrillation• Expressive aphasia• Hemothorax• Increased phosphokinase level• Infections• Laceration | <ul style="list-style-type: none">• Local hematomas/ecchymosis• Myocardial infarction• Pericardial effusion• Pericarditis• Pleural effusion• Pneumothorax• Pseudoaneurysm• Pulmonary edema• Pulmonary embolism• Seizure• Temporary complete heart block• Thrombi• Thromboembolism• Transient ischemic attack (TIA)• Valvular damage/insufficiency• Vascular bleeding• Vasovagal reactions• Ventricular tachycardia• Worsening chronic obstructive pulmonary disease |
|--|---|

For actual adverse events observed during the clinical study (within 7 days post-ablation), please refer to Table 18 below.

IX. SUMMARY OF PRECLINICAL STUDIES

The sponsor conducted preclinical and animal studies on the NaviStar™ and Celsius™ DS catheters, Stockert 70 generator, catheter interface cables and the Carto system. These tests are summarized below.

A. NaviStar™ DS Catheter

A.1. - Reliability

The sponsor performed reliability testing for the NaviStar™ DS catheter. In the tests described below, the catheters were single-sterilized prior to testing. Visual examinations noted below were conducted using a microscope.

Table 1 - Reliability Testing of NaviStar™ DS

Test	Sample Size	Acceptance Criteria	Results
Deflection	20	No mechanical failures before 200 cycles	passed*
Flex cycles	20	No mechanical failures before 10 cycles	passed
Gas pressure/joint seal	20	Minimum pressure 4.6 psi	passed
Torque Tip Electrode to Soft Tip Joint	5	No failure before 2.6 oz-in	passed
Torque Shaft to Tip Joint	5	No failure before 2 turns	passed
Torque Shaft to Piston Joint	5	No failure before 2 turns	passed
Pull Test Tip Electrode to Soft Tip Joint	5	No failure before 4 lbs	passed
Pull Test Shaft to Tip Joint	5	No failure before 4 lbs	passed

* In documenting results, "passed" means that all samples passed.

Tests not conducted

The main differences between the NaviStar™ DS catheter in this PMA and the NaviStar™ catheter approved under P990025 are the length of the tip electrode (8 mm vs. 4 mm, respectively) and the additional thermocouple in the present NaviStar™ DS catheter. Due to these similarities, the following reliability tests were not repeated in this PMA:

- Torque Barrel to Connector
- Torque Entire Catheter
- Torque Plot
- Pull Test Barrel to Connector
- Pull Test Entire Catheter
- Pull Test Shaft to Piston Joint

A.2. - Mechanical Performance

The sponsor performed mechanical performance testing for the NaviStar™ DS catheter. In these tests, the catheters were soaked for 5 hours in a 37 °C saline bath prior to testing (except for the buckle test).

Table 2 - Mechanical Performance Testing of NaviStar™ DS

Test	Sample Size	Acceptance Criteria	Results
Steering Through Vascular Model	20	No mechanical failures after 10 insertions	passed
Steering	20	No mechanical failures after 100 rotation cycles	passed
Bending Test	20	*Baseline testing at 50 g 100 g 150 g 200 g	0.23 " 0.32" 0.39" 0.45"
Tip Stiffness	20	<27 g	passed
Side Force*	20	>4 g	passed
Buckle Test**	20	none	20.9 – 38.2 gm

* Side force is the force needed to deflect the deflectable tip of the catheter 90 degrees.

** This test was designed to establish comparison to NaviStar™ 4mm results only.

A.3. - Electrical Performance

Electrical performance testing was conducted on catheters sterilized five times during the qualification test (pre- and post-simulated ablation) to evaluate whether electrical performance was compromised during the test cycle. All test samples met the established acceptance criteria for electrical performance testing. See Table 3 below.

Table 3 - Electrical Performance Testing of NaviStar™ DS

Test	Sample Size	Acceptance Criteria	Results
DC Lead Resistance	20	<10 Ω and within 0.4 Ω of each other	passed
DC Isolation Resistance	20	>200 kΩ	passed
RF Lead Impedance @ 5 kHz	20	<10 Ω	passed
RF Lead Impedance @ 500 kHz	20	<25 Ω	passed
RF Isolation Impedance @ 5 kHz	20	>100 kΩ Phase angle between -86° to -90°	passed
RF Isolation Impedance @ 500 kHz	20	>1 kΩ Phase angle between -86° to -90°	passed
Temperature Reading - Thermocouple Sensor (2ea) (not using Stockert generator)	10	60 ± 2°C	passed
Verify PCB Calibration	20	Calibration results read "OK"	passed
RF Leakage Current	20	< 290 mA	passed

A.4. - Simulated Use of NaviStar™ DS

Simulated use ablation using a beef heart in a 37°C saline bath was conducted to evaluate the functional performance of the catheter, cables, and CARTO system. Each NaviStar™ DS catheter was visually inspected for mechanical failures post-ablation. Lesion volume was measured for 10 of the 20 catheters, and was found to be comparable for all lesions and catheters. Compared to the NaviStar™ 4mm Catheter results, the mean DS lesion volume was greater by 131mm³ when RF energy was applied at 50W for one minute.

Table 4 - Functional Performance Testing of NaviStar™ DS

Name of Test	Sample Size	Acceptance Criteria	Results
Visual Inspection Post-Ablation	20	No anomalies	passed
Lesion Volume	10	Consistent lesions should be created	354 mm ³ (mean) Consistent lesions were produced

A.5. - Electromagnetic Compatibility of NaviStar™ DS

Electromagnetic compatibility (EMC) testing was not conducted on the NaviStar™ DS catheter, due to similarity with the NaviStar™ 4 mm catheter approved under P990025.

A.6. - Electrical Safety of NaviStar™ DS

Electrical safety testing was not conducted on the NaviStar™ DS catheter, because no changes (as compared to the catheter approved under P990025) were made to the Carto and Stockert power distribution and electrical isolation subsystems.

A.7. - Biocompatibility and Sterilization of NaviStar™ DS

Since the NaviStar™ DS catheter and the NaviStar™ 4 mm catheter approved under P990025 have the same patient contacting materials, biocompatibility and sterilization via ethylene oxide (ETO) were not re-validated. By extension, the same conclusion is applicable to the Celsius™ DS catheter.

The following table lists the patient and user contacting materials that were tested in accordance with ISO 10993 and submitted under P990025. All materials are classified as short duration, direct blood path, and externally communicating per ISO 10993-1.

Table 5 - Patient Contacting Materials of the DS Catheter

Material Spec No.	Component	Material Description
M-5439-03	Deflectable Tip	55D Pellethane
M-5013-04 M-5203-111	Ring and Tip Electrodes	90%/10% Platinum/Iridium
M-5439-05	Flexible Shaft	75D Pellethane
P-9749-03	Sensor Housing	Polyetherether ketone
P-9231	Shaft to Tip Adhesive	Polyurethane

A.8. - DS Catheter Upper Allowable RF Application Limit

The sponsor evaluated the maximum number of RF applications that the NaviStar™ DS catheters may perform. A total of 16 samples were tested. Each catheter was used to create 125 RF ablations of 1 minute duration applied to a sponge in a saline bath. The temperature characteristics of the sponge was found to be equivalent to beef heart. All catheters were subjected to electrical testing pre- and post-ablation, with satisfactory results. Reliability testing (200 deflections, tensile strength of the PEEK to tip electrode joint), temperature accuracy, mapping capability, and torque testing were performed post-ablation. All the NaviStar™ catheters passed. The test results support the sponsor's ability to label the catheter for up to 70 one-minute applications.

A. 9. - Animal Testing of NaviStar™ DS

Animal studies were conducted to characterize the safety, effectiveness, and performance of the NaviStar™ DS catheter in dog models. Both in-vivo and in-vitro, or thigh muscle preparation studies were performed.

The in-vivo testing was performed on 9 dogs. Electrophysiological testing was performed to measure the presence of conduction block across the tricuspid valve isthmus. All animals had a linear lesion on postmortem exam. The lesions were visible on endocardial and epicardial surfaces. The mean total length of the lesion was 30±8mm (range 19-36mm) and the mean maximum width was 7±2mm (range 4-9mm). Histology showed that there was transmural coagulative necrosis of myofibers, and fibrosis with preservation of overall architecture.

Additional in-vivo testing performed on 2 dogs using the thigh muscle preparation and inside the LV. These studies were performed to measure temperature differential between the tip electrode thermocouple and interface temperature in the tissue when the catheter was perpendicular vs. parallel to the animal tissue. The maximum temperature differential seen between the tip electrode thermocouple and the interface temperature was recorded with the catheter in the perpendicular orientation and with maximum blood flow. This result demonstrates the cooling effect of the blood on the surface of the tip electrode.

A.10. - Shelf Life of NaviStar™ DS

The NaviStar™ DS catheter sterile packaging is identical to the NaviStar™ 4 mm catheter approved in PMA P990025. The mechanical and electrical properties of the NaviStar™ DS catheter are similar to that of the NaviStar™ catheter approved under P990025. Therefore, a shelf life claim of one (1) year is acceptable, as approved under P990025.

B. Celsius™ DS Catheter

The Celsius™ DS catheter is similar to the NaviStar™ DS catheter in most aspects, except it does not include the location sensor. In addition, the Celsius™ DS catheter is similar to the Celsius™ catheter approved under P950005 with these exceptions: (1) the electrode tip length is 8 mm vs. 4-5 mm; and (2) the number of thermocouples is 2 vs. 1. All other design features proximal to the tip electrode are identical. As a result, many tests performed on the NaviStar™ DS catheter (described above), and previously conducted on the Celsius™ Catheter (reference P950005) are not repeated on the Celsius™ DS catheter.

The verification test results for the Celsius™ DS catheter are summarized below:

B.1. - Reliability

The sponsor performed reliability testing for the Celsius™ DS catheter, as summarized below.

Table 7 - Reliability Testing of Celsius™ DS

Test	Sample Size	Acceptance Criteria	Results
Deflection	20	No mechanical failures before 200 cycles	passed
Flex cycles	20	No mechanical failures before 10 cycles	passed
Gas pressure/joint seal	20	Minimum pressure 4.6 psi	passed
Torque Barrel to Connector	10	≥ 9 oz-in before failure	passed
Torque Entire Catheter	16	> 2 turns before failure	passed
Torque Tip Electrode to Soft Tip Joint	5	≥2.6 oz-in before failure	passed
Torque Shaft to Tip Joint	5	> 2 turns before failure	passed
Torque Plot	20	≥ 2 turns before failure	passed
Torque Shaft to Piston Joint	5	> 2 turns before failure	passed
Pull Test Barrel to Connector	5	≥4 lbs before failure	passed
Pull Test Entire Catheter	20	≥ 4 lbs before failure	passed
Pull Test Tip Electrode to Soft Tip Joint	5	≥ 4 lbs before failure	passed
Pull Test Shaft to Tip Joint	5	≥ 4 lbs before failure	passed
Pull Test Shaft to Piston Joint	5	≥ 4 lbs before failure	passed
Deflection Force	20	< 10 lbs before failure	passed

B.2. - Mechanical Performance

The sponsor performed mechanical testing for the Celsius™ DS catheter, as summarized below. The catheters were soaked for 5 hours in a 37°C saline bath prior to testing (except for the buckle test).

Table 8 - Mechanical Performance Testing of Celsius™ DS

Test	Sample Size	Acceptance Criteria	Results
Steering Through Vascular Model	20	No mechanical failures before 10 insertions	passed
Steering	20	No mechanical failures before 100 rotation cycles	passed
Tip Stiffness	20	<27 g	passed
Side Force	20	>4 g	passed
Buckle Test	20	< 283 gm	10.8 –22.5 gm

B.3. - Electrical Performance

Electrical performance testing was conducted on catheters sterilized five times during the qualification test (pre- and post-simulated ablation) to ensure that electrical performance was not compromised during the test cycle. All test samples met the established acceptance criteria for electrical performance testing.

Table 9 - Electrical Performance Testing of Celsius™ DS

Test	Sample Size	Acceptance Criteria	Results
DC Lead Resistance measured at pre-soak, post-soak and during simulated ablation	20	<10 Ω and within 0.4 Ω of each other	all passed pre-soak. 1 failed post soak; 1 failed during simulated ablation*
DC Isolation Resistance	20	>200 k Ω	passed
RF Lead Impedance @ 5 kHz	20	<10 Ω	passed
RF Lead Impedance @ 500 kHz	16	<25 Ω	passed
RF Isolation Impedance @ 5 kHz	16	>100 k Ω Phase angle between -86° to -90°	passed
RF Isolation Impedance @ 500 kHz	16	>1 k Ω Phase angle between -86° to -90°	passed
RF Leakage Current	20	\geq 290 mA	passed

* Root cause was found and resolved by operator re-training.

Additionally, the Celsius™ DS catheter was tested for accuracy in temperature sensing in connection with the Stockert generator. All 20 Celsius™ DS catheters complied with the pass/fail criterion of $\pm 5^\circ$ C.

B.4. - Simulated Use of Celsius™ DS Catheter

Simulated use ablation using a beef heart in a saline bath was conducted to evaluate the functional performance of the Celsius™ catheter and cables. Each Celsius™ DS catheter was visually inspected for mechanical failures post-ablation. Lesion volume was measured for 10 of the 20 catheters, and was found to be comparable for all lesions and catheters. Compared to the NaviStar™ 4 mm Catheter results, the mean lesion volume of 376.26 mm³ was greater by 154 mm³.

Table 10 – Functional Performance Testing of Celsius™ DS

Name of Test	Sample Size	Acceptance Criteria	Results
Visual Inspection Post-Ablation	16	No anomalies	passed
Lesion Volume	10	Consistent lesions should be created for 10 catheters	376 mm ³ mean Consistent lesions were produced

B.5. - Electromagnetic Compatibility of Celsius™ DS

Electromagnetic compatibility (EMC) testing was not conducted on the Celsius™ DS catheter, due to similarity with the NaviStar™ 4 mm catheter approved under P990025.

B.6. - Electrical Safety of Celsius™ DS

Electrical safety testing was not conducted on the Celsius™ DS catheter, because of the similarity of the electrical safety characteristics to the NaviStar™, previously established under P990025.

B.7. - Animal Testing of Celsius™ DS

Due to the similarity of the Celsius™ with the NaviStar™ DS catheter, no animal testing was performed on the Celsius™ DS catheter.

B.8. - Shelf Life of Celsius™ DS

The Celsius™ DS catheter sterile packaging is identical to the Celsius™ 4 mm catheter approved under P950005. The mechanical and electrical properties of the Celsius™ DS catheter are similar to that of the NaviStar™ catheter approved under P990025. Therefore, a shelf life claim of one (1) year is acceptable, as approved under P990025.

C. Stockert 70 RF Generator

Based on the modifications made for this new version of the generator (see Device Description for details of differences between the version approved under P990071), pre-clinical testing performed on the device was limited to performance and software verification activities related to the dual thermocouple feature and the delivery of RF power up to 70 W.

C.1. - Performance Verification

Below is a summary of the performance verification activities performed:

Table 11 – Stockert 70 Verification Tests

Test	Sample Size	Acceptance Criteria	Results
Thermocouple Response Time	1 generator and 20 catheters	< 10 sec	passed
Temperature Cutoff	20	± 5°C	passed
Detect catheter disconnect	1 generator	Overflow condition 999.9°C displayed	passed
Temperature Accuracy	1 generator	± 5°C	passed

C.2. - Software on the Stockert 70 Generator

The software in the Stockert 70 was modified to read two temperature readings from the thermocouple sensors, and select the higher of the two for temperature display and control, and to allow the delivery of up to 70 W of RF power. Software validation was limited to verifying that the correct temperature was displayed given two thermocouple inputs. Bench testing verified that the correct RF power was delivered in the range from 50 to 70 W.

D. Catheter Interface Cables

The two types of catheter interface cables, D-1195 (connects the NaviStar™ DS catheter to junction box) and D-1170 (connects the Celsius™ DS catheter to Stockert 70 generator), were tested.

D.1. - D-1195 Catheter Interface Cable

The testing performed on the D-1195 cable is summarized below.

Table 12 – D-1195 Cable Verification Test Summary

Test	Sample Size	Acceptance Criteria	Results
Package Inspection	18	No seal voids, holes, damage	passed
Electrical Resistance	18	Pin 14, 12-20 Ω Pins 2-13 & 15-25, <3 Ω	passed
Connection Cycles	18	Withstand 100 mate/unmate cycles No disconnect with 7 lbs applied force	passed passed
Electrical Resistance	18	Pin 14, 12-20 Ω Pins 2-13 & 15-25, <3 Ω	passed
Dielectric Withstand	18	Record voltage	N/A
Leakage Current	18	< 1 μ A pin to pin	passed
Cable Twist	18	Verify continuity and isolation of all conductors	passed
Axial Pull	18	Withstand 15 lbs	passed
Cable Coil	18	Verify continuity and isolation of all conductors	passed
Cable Flex	18	Verify continuity and isolation of all conductors	passed

D.2. - D-1170 Catheter Interface Cables

Design verification tests were not repeated for the D-1170 cables since they are almost identical to the D-1195 design. The tests were designed to conform with ANSI/AAMI EC53-1995, and are summarized below.

Table 13 - D-1170 Cable Verification Tests

Test	Sample Size	Acceptance Criteria	Results
Visual Examination	30 (3 lots of 10)	No visual anomaly	passed
Electrical Resistance	30	Pins 1-5,7,8 <3 Ω Pins 6,9 12-20 Ω	1/30 failed at pin #7*
DC Isolation	30	>200 Ω	1/30 failed*
Temperature Test	30	60 \pm 5 $^{\circ}$ C	1/30 failed*
Electrode to ECG	30	< 15 Ω	passed

* Root cause of the cable failures was found and resolved via operator re-training.

E. Junction Box/Patient Interface Unit (PIU)

The junction box (or patient interface unit) from the Carto XP system was modified to enable communication of the second thermocouple voltages from the NaviStar™ and Celsius™ DS catheters to the Stockert 70 generator using the modified D-1170 and D-1195 cables.

The verification tests involved conducting ablation studies on beef heart strips immersed inside a temperature controlled saline tank. The system was challenged in both temperature and power control modes to verify proper functioning of the DS catheter and that proper error messages appeared on the Stockert generator when ablation with other catheters was attempted after selecting the “8mm Dual TC” menu. Proper functioning of the Carto mapping system and RefStar location pad was also verified. All results were acceptable in Power and Temperature control modes.

X. SUMMARY OF CLINICAL STUDIES

The clinical testing described below was performed with the NaviStar™ DS catheter, and not with the Celsius™ DS catheter. Since the ablation capabilities of both NaviStar and Celsius™ DS catheters were shown with pre-clinical testing to be similar, clinical testing results from the NaviStar™ study, as reported below, may be extrapolated to what would be expected when using the Celsius™ DS catheter.

A. Objective

The objective of the study was to determine if the NaviStar™ DS catheter, when used in conjunction with the Stockert 70 RF generator and related accessory devices, is safe and effective for the treatment of Type 1 atrial flutter in patients age 18 or older.

B. Study Design

The study was a prospective, non-randomized, unblinded, multi-center study conducted at 16 investigational sites.

B.1. - Study Endpoints:

The endpoints for the study were as follows:

- **procedural safety** - defined by the absence of serious complications associated with the use of the investigational device within seven days of the ablation procedure; and
- **acute procedural success** - defined as complete bi-directional conduction block across

the isthmus, and the inability to induce typical atrial flutter post-procedure.

Long-term freedom from atrial flutter recurrence was not specifically identified as a study endpoint. Instead, FDA allowed acute procedural success to be used as a surrogate endpoint for this parameter. Long-term (defined as 6-months post-treatment) freedom from atrial flutter recurrence information was also collected, in order to enable FDA to assess whether the surrogate endpoint was reasonable.

B.2. - Objective Performance Criteria (OPC):

Objective performance criteria (OPC) were prospectively established for all atrial flutter studies by FDA, based on prior experience with supraventricular tachycardia (SVT) ablation studies and consideration by the FDA Circulatory System Devices Panel. The OPC are defined below:

- **Safety:** major adverse events within 7 days of the procedure occur at a rate of **2.7%** or less with a **7%** one-sided 95% confidence bound;
- **Acute success:** **88%** with an **80%** one-sided 95% confidence bound.

B.3. - Patient Accountability

The table below documents the accountability of patients throughout the study.

Table 13(a) - Patient Accountability

Patients enrolled in study	191
Patients not ablated	9
Patients ablated with NaviStar	182
Patients ablated only with NaviStar	166
Patients ablated with NaviStar and non-investigational catheter*	15
Patients found to have atypical atrial flutter post ablation**	1

* Patients were first ablated with the NaviStar only. If flutter procedure could not be completed, then physicians used another catheter to complete procedure. These patients were considered acute effectiveness failures.

** This patient was considered acute effectiveness failure, as documented in Table 16 below.

B.4. - Patient Demographics

The table below summarizes the demographic information of patients enrolled in the study.

Table 13(b) - Patient Demographics (n=182)

Gender	n	%
Female	39	21.43%
Male	143	78.57%
Age (in years)		
mean + standard deviation	64.27 ± 10.20	
Median	65.00	
range	37-87	

In addition, seventy-eight (78) patients were reported with a total of 131 reported concomitant arrhythmias. The most common arrhythmia was atrial fibrillation, reported in 85 cases.

C. Results

C.1. - Intraprocedural Data

The table below describes the intraprocedural data:

Table 14 - Power, Temperature and Impedance Data

Description	Mean ± Standard Deviation	Range
# RF applications/procedure ¹ (n=182 procedure)	24.1 ± 19.7	4-134
maximum power (Watts)/application ² (n=4368 RF applications)	52.5 ± 10.4	10-87
maximum temperature (°C)/application ² (n=4387 RF applications)	52.3 ± 7.4	23-85
maximum impedance (Ohms)/application ² (n=4346 RF applications)	92.4 ± 17.0	37-258

- ¹-One patient had a second ablation procedure.
 -One patient was missing RF information.
 -One patient received 134 applications ≥ 5 seconds.
 -One patient was ablated for a non-protocol arrhythmia.

² Power, temperature, and impedance not documented for several RF applications.

Table 15 - Fluoroscopy/Procedure Time (minutes)

Description	Mean ± Standard Deviation	Range
total fluoroscopy time/procedure ¹ (n=176 procedures)	31 ± 30	2-198
total procedure time/procedure ¹ (n=178 procedures)	164 ± 145	36-595

¹Incomplete fluoroscopy times were reported for six (6) patients and incomplete procedure times were reported for four (4) patients.

C.2. - Acute Procedural Success

Acute procedural success evaluation was based on 182 patients treated with the NaviStar. The table below describes this information:

Table 16 - Acute Ablation Outcomes (n=182)

	# Success/# Patients Ablated	Percentage (1-sided 95% confidence bound)¹
Acute Study Results	164/182	90.11% (87.22%)
OPC		88% (80%)

¹Exact binomial using a commercially-available software package.

C.3. - Freedom from Atrial Flutter Recurrence at Six-Month Follow-Up

Freedom from atrial flutter recurrence was evaluated in patients in whom bi-directional tricuspid isthmus conduction block (BDB) was achieved and for whom 6-month post-ablation information was available. Based on these criteria, information was available on a total of 112 patients. Results are described in Table 17 below.

Table 17 - Freedom from Atrial Flutter at 6 months

Description	N
Patients with successful BDB	112
# patients free from recurrence	105 (93.75%)
# patients with recurrence of atrial flutter	7
# patients free from both recurrence and medication change (percentage based on N=112)	98 (87.50%)
# patients with anti-arrhythmic drugs (AAD) changes to treat atrial fibrillation	9
Patients ablated only with NaviStar and successful BDB	108
# patients free from recurrence	102 (94.44%)
# patients with recurrence of atrial flutter	6
# patients free from both recurrence and medication change (percentage based on N=108)	95 (87.96%)
# patients with AAD changes to treat atrial fibrillation	8
# patients with anti-arrhythmic drugs to treat VT	1

These results provide reasonable evidence that acute procedural success serves as an appropriate surrogate for long-term freedom from atrial flutter recurrence.

C.4. - Adverse Events and Deaths

An adverse event was determined to be any undesirable experience occurring to a subject during the course of the study, whether or not it is related to the device or procedure. A major adverse event was defined as any clinical event resulting in death, a life-threatening complication, or a persistent or significant disability/incapacity that requires inpatient hospitalization or prolongs hospitalization or requires intervention to prevent a permanent impairment of a body function or damage to a body structure.

Major Adverse Events

Of the 182 patients treated with the NaviStar, fourteen (14) major adverse events were reported in thirteen (13) patients. The major adverse event rate (number of patients with the major adverse events per the number of patients in the study) observed with the use of the NaviStar™ DS catheter was 7.14% (13/182), and the 95% upper confidence bound was 10.97%.

A risk/benefit analysis was performed and a detailed review of each adverse event was completed. Several patients had adverse events related to pre-existing non-cardiac disease. Several patients had adverse events related to having an invasive procedure but not relating specifically to an ablation procedure or the investigational device. The table below summarizes the major adverse event (AE) information.

Table 18 - Major Adverse Events, observed within 7 days post-ablation

	# AEs ¹
Dysrhythmias	
Exacerbation of pre-existing atrial fibrillation ²	3
Temporary complete heart block, required pacing ²	1
Ventricular tachycardia during electrophysiology study, required ICD	1
Atypical flutter ²	1
Exacerbation of pre-existing disease	
Pulmonary	1
Congestive heart failure	1
Neurological	2
Vascular entry related	
Pneumothorax	1
Pseudoaneurysm	1
Anemia	1
Sedation/restraint related	
Rotator cuff tendon tear	1

¹ One patient had 2 events (exacerbation of pre-existing atrial fibrillation and pneumothorax).

² Possibly related to use of device.

As noted in the above table, a total of five (5) major adverse events were determined to be possibly device-related (for a device-related AE rate of 5/182 or 2.7%).

Two patients died during the course of the study. Neither death was temporally related to the ablation procedure. One death was unwitnessed and occurred 5 months after the ablation procedure in a 59 year old man who also had hypertension, diabetes, peripheral vascular disease, congestive heart failure, atrial fibrillation and coronary artery disease. No autopsy was performed. The other patient death occurred two months after the procedure in an 82 year old man due to pneumocystis pneumonia thought to be secondary to his pre-existing chronic lymphoid leukemia.

C.5. - Statistical Analysis

The table below summarizes the safety and effectiveness of the device when compared to the control group OPC established for safety and acute success.

Table 19 - Comparison of Endpoints between NaviStar™ DS Study and OPC

Endpoint	OPC		NaviStar™ DS Study	
	%	One-sided 95% Confidence Bound ¹	% (N)	One-sided 95% Confidence Bound ¹
Acute Success	88%	80%	90.11% (164/182)	87.22% (Lower bound)
Major Complications	2.7%	7%	7.14% (13/182)	10.97% (Upper bound)

¹Exact binomial using a commercially-available software package.

By comparing the lower bounds of the acute success endpoints (87.22% vs. 80%), the results demonstrate that the NaviStar™ DS catheter met the OPC for acute success. As previously explained, although the device exceeded the upper bound of major complications, review of the specific events revealed that most events were not device-related; accordingly, the adverse event rate was acceptable.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

Pre-clinical testing demonstrates that the NaviStar™ DS catheter, Celsius™ DS catheter, Stockert 70 RF Generator and accessories (cables and junction box) will maintain mechanical and electrical integrity under the proposed conditions of use. Additionally, biocompatibility testing of the patient-contacting materials demonstrates that the devices are biocompatible under the proposed conditions of use.

Clinical testing and statistical analyses demonstrate that the NaviStar™ DS and Celsius™ DS catheters when used with the Stockert 70 RF generator is reasonably safe and effective for the treatment of Type 1 atrial flutter.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System 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.

XIII. CDRH DECISION

CDRH issued an approval order on September 27, 2002. The applicant's manufacturing facilities were inspected on March 14, 2001 and March 16, 2001 and found to be in compliance with the device Quality System Regulation (Part 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

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