P990025

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

P990025, Biosense Webster, Inc.

NAVI-STAR® Diagnostic/Ablation Catheter

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Summary of Safety and Effectiveness Data

1.1 GENERAL INFORMATION

Device Generic Name:	Diagnostic/Ablation Catheter
Device Trade Name(s):	NAVI-STAR® Diagnostic/Ablation Catheter
Device Model Numbers:	NAVI-STAR® Diagnostic/Ablation Catheter, D-1183/D-1184 *Catheter interface cables, D-1195 *As approved under P950005(Celsius)
Applicant's Name and Address:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765
PMA Number:	P990025
Date of Panel Recommendation:	N/A
Date of Notice of Approval to the Applicant:	JUN 15 2000

1.2 INDICATIONS FOR USE

The NAVI-STAR® Diagnostic/Ablation Catheter, and related accessory devices are indicated for catheter-based atrial and ventricular cardiac mapping, and when used with a compatible radiofrequency generator in adults and children 4 years of age and older for:

- interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia; including persistent junctional re-entrant tachycardia (PJRT) and Mahaim fibers;
- the treatment of AV nodal re-entrant tachycardia; and
- creation of complete AV nodal block in patients with a difficult to control ventricular response to an atrial arrhythmia.

When used with the CARTO® EP Navigation System. the NAVI-STAR® Diagnostic/Ablation catheter provides location information.

1.3 CONTRAINDICATIONS

Do not use this device;

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch;
- via the retrograde transaortic approach in patients with aortic valve replacement.

1.4 WARNINGS AND PRECAUTIONS

See Warnings and Precautions in the final approved labeling (Instructions for Use).

1.5 DEVICE DESCRIPTION

The NAVI-STAR® catheter and related accessory devices, is designed to acquire and analyze individual data points during mapping of the atrial and ventricular structures of the human heart. For ablation, the catheter is used in conjunction with a compatible RF generator and required accessories.

1.5.1 Procedure Components

The following commercially available devices are required to conduct an EP procedure:

- grounding pad (dispersive pad);
- electrocardiogram (ECG) leads;
- electrophysiology (EP) recording equipment;
- compatible radiofrequency (RF) generator; and
- pacing stimulator.

The above devices are sold separately, and are not covered by this PMA application.

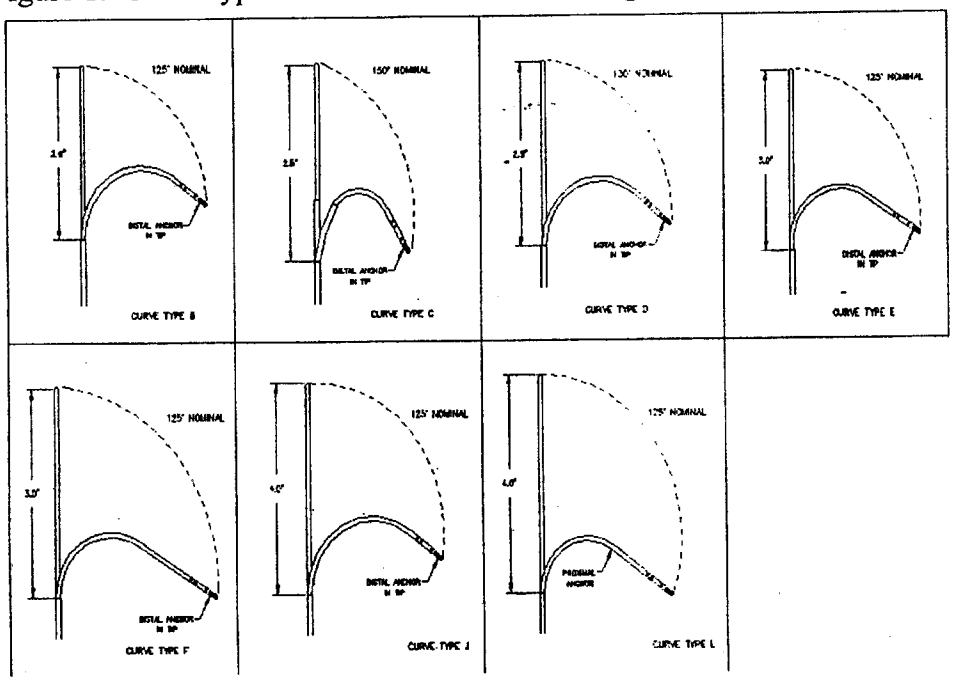
1.5.1.1 NAVI-STAR® Diagnostic/Ablation Catheter

The NAVI-STAR® catheter is a steerable, multi-electrode catheter with a deflectable tip. The catheter provides information for electrophysiological mapping of the heart and transmits RF current through the catheter tip electrode for ablation purposes. When used with the CARTO® system and REF-STAR® reference device, a real-time 3D reconstruction of the heart chamber is provided. For ablation, the catheter is used in conjunction with a compatible RF generator and a commercially available dispersive pad.

The NAVI-STAR® catheter is a 7 F catheter with a usable length of 115 ± 3 cm; the device is provided sterile (EtO). The device has a high-torque polyurethane shaft with a deflectable tip section containing an array of platinum electrodes. All electrodes may be used for recording and stimulation, but only the tip electrode may be used to deliver RF energy from the generator. A magnetic location sensor embedded in the tip electrode transmits location information to the CARTO® system. The catheter is available with either a thermocouple or thermistor temperature sensor.

Tip deflection is controlled at the proximal end by a tubular handpiece in which a piston slides; a thumb knob on the piston controls piston travel. The plane of the curved tip can be rotated and the shape of the curve depends on the deflectable tip length and the location of the puller-wire anchor in the deflectable tip. Seven curve types, designated "B" through "F," "J," and "L" are available as shown in Figure 1. The catheter interfaces with the CARTO® system and a compatible RF generator via an interface cable and a junction box.

Figure 1. Curve types for the NAVI-STAR® Diagnostic/Ablation Catheter.



1.6 DEVICE MODEL NUMBERS

Manufacturing Part No.	U.S. Catalog No.	Description
D-1183	NS7TC-BL-174-HS NS7TC-CL-174-HS NS7TC-DL-174-HS NS7TC-EL-174-HS	NAVI-STAR® 7F catheter with thermocouple temperature sensor, 4 mm tip electrode, 1-7-4 mm spacing, Hypertronics connector, provided

	NS7TC-FL-174-HS NS7TC-JL-174-HS NS7TC-LL-174-HS	sterile
D-1184	NS7T-BL-174-HS NS7T-CL-174-HS NS7T-DL-174-HS NS7T-EL-174-HS NS7T-FL-174-HS NS7T-JL-174-HS NS7T-LL-174-HS	NAVI-STAR® 7F catheter with thermistor temperature sensor, 4 mm tip electrode, 1-7-4 mm spacing, Hypertronics connector, provided sterile
D-1195	C5-MH/REFMH-S C5-MH/NAVMH-S C5-MH/XRFMH-S	NAVI-STAR® interface cables for use with the CARTO® system

The U.S. catalog numbers for the NAVI-STAR® catheters are "smart numbers" containing basic information regarding the device, as follows:

NS7	=	NAVI-STAR® 7 F device
TC	=	Thermocouple temperature sensor
T	=	Thermistor temperature sensor
B,C,D,E,F,J, L	=	Available curve types
L	=	Large dome (4mm tip electrode)
174	=	Ring electrode spacing
H	=	Hypertronics connector
S	=	Sterile product

The smart numbers for the catheter interface cables contain the following information:

C5	=	5 foot extension cable
MH	=	Hypertronics connector
REF	=	For use with REF-STAR® catheter
NAV	=	For use with NAVI-STAR® catheter
XRF	=	For use with REF-STAR® External Reference Patch
S	=	Sterile product

1.6.1.1 Catheter Interface Cables

Biosense Webster manufactures a variety of interface cables for use with its diagnostic/ablation catheters and the CARTO® system. The catheter interface cables for use with the NAVI-STAR® catheter and REF-STAR® devices have locking connectors on both ends. The cables connect the NAVI-STAR® and REF-STAR® catheters to a junction box. Biosense Webster's market-approved generator interface cables connect the junction box to a compatible RF generator. A description of these cables can be found in P950005. A description of the REF-STAR® and CARTO® system can be found in K000248.

1.6.2 Compatible Radiofrequency Generators

The NAVI-STAR® catheter should be used only with a legally marketed, compatible RF generator which has been shown to be safe and effective for cardiac ablation. The following table lists specifications for compatible RF generators.

SPECIFICATIONS FOR COMPATIBLE RF GENERATORS

Generator	Specification
Thermometry	Thermocouple or Thermistor
Temperature Limit, Maximum	100°C
Modes: (must operate in all 3 modes)	Temperature Control Temperature Monitoring Power Control
Maximum Output Power	50 Watts
RF Output Frequency	450kHz – 550kHz
Impedance Cut-off	High: 250Ω Low: 40Ω

1.7 ALTERNATIVE PRACTICES AND PROCEDURES

Alternative therapy for cardiac arrhythmia includes direct surgical ablation, use of drugs for tachycardia control, antitachycardia pacing, and RF ablation with various market-approved catheters. All of the alternative ablation catheters are placed and moved within the heart using fluoroscopy.

1.8 MARKETING HISTORY

The NAVI-STAR® Diagnostic/Ablation Catheter has not been marketed in the United States. The NAVI-STAR® Diagnostic/Ablation Catheter is available for sale in Canada, Europe, and South America.

There are no countries from which the NAVI-STAR® catheter, or the related accessory devices, have been withdrawn from marketing for any reason related to safety or effectiveness.

1.9 ADVERSE EFFECTS OF THE DEVICE ON HEALTH

1.9.1 Observed Adverse Events

The Biosense Webster NAVI-STAR® Diagnostic/Ablation Catheter was studied in 320 enrolled patients undergoing electrophysiologic (EP) mapping and RF catheter ablation to eliminate atrioventricular (AV) accessory pathways (AP) associated with tachycardia due to Wolff-Parkinson-White (WPW) syndrome, AV nodal re-entrant tachycardia

(AVNRT), or creation of complete AV nodal (AVN) block in patients with difficult to control ventricular response to an atrial arrhythmia.

Three hundred twenty (320) patients were enrolled in the clinical study. Two hundred eighty-one (281) enrolled patients underwent RF ablation. These patients were followed for a mean of 8.22 months with a standard deviation of 4.37. The maximum length of follow-up was 20.39 months. All 281 patients undergoing RF ablation were included in the safety database.

Sixteen adverse events were reported for the 281 patients who received ablation therapy; seven of these events were classified as major adverse events. Major and minor adverse events were classified according to the FDA's recommended definitions for evaluating ablation safety. The major adverse events, occurring within seven days post ablation, included complete heart block that required placement of a permanent pacemaker (2 patients); atrial puncture caused by a transseptal sheath (1 patient); retroperitoneal hemorrhage resulting from a groin stick for venous access (1 patient); minor (non-q-wave) myocardial infarction (1 patient), cardiac tamponade (1 patient), and pulmonary edema (1 patient).

Minor adverse events included tricuspid regurgitation (2 patients); transient heart block (1 patient); pericardial effusion (1 patient) and dehydration (1 patient), dermal hypersensitivity (1 patient), femoral pseudoaneurysm (1 patient), mild fever with myalgia (1 patient), and trace pericardial effusion (1 patient).

Three deaths were reported for the study (the patients expired 12 days, 34 days, and 49 days, respectively, post-procedure). All deaths were due to complications associated with the patient's primary disease condition.

A summary of observed adverse events for all ablated patients is provided in the following table:

Observed Adverse Events/Deaths (N=281)

Adverse Event Classification	% patients	Number of patients	95% Confidence Interval*	
Major	2.5%	7/281	0.010	0.053
Minor	3.2%	9/281	0.015	0.061
Death	1.1%	3/281	0.002	0.034

*Confidence intervals by exact (binomial) method

1.9.2 Anticipated Adverse Events

Adverse events (in alphabetical order) which may be associated with catheterization and ablation include:

- Air embolism
- Arrhythmias
- AV fistula
- Cardiac perforation/tamponade
- Cardiac thromboembolism
- Cerebrovascular accident (CVA)
- Chest pain/discomfort
- Complete heart block
- Coronary artery dissection
- Coronary artery spasm
- Coronary artery thrombosis
- Hemothorax
- Increased phosphokinase level.
- Laceration
- Local hematomas/ecchymosis
- Myocardial Infarction
- Pericardial effusion
- Pericarditis
- Pleural effusion
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism/tamponade
- Thrombi
- Thromboembolism
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular damage
- Vascular bleeding/local hematomas
- Vasovagal reactions
- Ventricular tachyarrhythmia

1.10 SUMMARY OF PRECLINICAL STUDIES

Nonclinical bench testing and animal testing have been conducted to demonstrate the safety and reliability and performance specifications of the NAVI-STAR® Catheter. The following sections summarize the results of this testing.

1.10.1 Bench Testing on Physical Properties of the NAVI-STAR® Catheter and REF-STAR® Catheter

Design verification testing of the NAVI-STAR® catheter was conducted to establish conformance with applicable standards and FDA guidance documents. (For the purpose of this test, the NAVI-STAR® catheter was chosen as the worst-case example for the NAVI-STAR® family of devices.)

Using standard methods consistent with the ANSI standard for Electrosurgical Devices (HF-18), AAMI standards for ECG connectors (ECGC), and the agency's "Electrode Recording Catheter Preliminary Guidance" (1995) and the "Cardiac Ablation Preliminary Guidance" (1995), the catheter design was evaluated to demonstrate structural integrity and design performance. The integrity of the shaft, tip electrode, sensor housing, location sensor, and temperature sensors were tested on the bench, and under simulated use conditions. Reliability testing was conducted on sterilized catheters. The catheters were

evaluated for fatigue resistance, joint integrity, torsion, and tensile strength. All test samples met the established acceptance criteria for reliability testing.

RELIABILITY TESTING

Test	Number	Acceptance Criteria	Results
Deflection	20	No mechanical failures before 200 cycles	All samples passed
Flex cycles	20	No mechanical failures before 10 cycles	All samples passed
Gas pressure/joint seal	20	Minimum pressure 4.6 psi	All samples passed
Torque Barrel to Connector	10	Withstands $\geq$ 9 oz-in	All samples passed
Torque Entire Catheter	5	Withstands > 2 turns	All samples passed
Torque Tip Electrode to Soft Tip Joint	5	Withstands $\geq$ 2.6 oz-in	All samples passed
Torque Shaft to Tip Joint	5	Withstands > 2 turns	All samples passed
Torque Plot*	20	Withstands > 2 turns	All samples passed
Torque Shaft to Piston Joint	5	Withstands > 2 turns	All samples passed
Pull Test Barrel to Connector	10	Withstands $\geq$ 15 lbs	All samples passed
Pull Test Entire Catheter	5	Withstands $\geq$ 4 lbs	All samples passed
Pull Test Tip Electrode to Soft Tip Joint	5	Withstands $\geq$ 4 lbs	All samples passed
Pull Test Shaft to Tip Joint	5	Withstands $\geq$ 4 lbs	All samples passed
Pull Test Shaft to Piston Joint	5	Withstands $\geq$ 4 lbs	All samples passed

Mechanical performance testing was conducted on sterilized catheters. All test samples met the established acceptance criteria for mechanical testing.

MECHANICAL PERFORMANCE TESTING

Test	Number of Devices Tested	Acceptance Criteria	Results
Soak	20	No mechanical failures after 5 hour soak in 37°C saline bath	All samples passed
Steering Through Vascular Model	20	No mechanical failures before 20 insertions	All samples passed
Steering	20	No mechanical failures before 100 cycles	All samples passed
Bending Test	20	Baseline testing of catheter deflection with masses of: 50 g 100 g 150 g	All samples passed (characterization test: no set acceptance

MECHANICAL PERFORMANCE TESTING

Test	Number of Devices Tested	Acceptance Criteria	Results
		200 g	criteria)
Tip Stiffness	20	Stiffness <27 g	All samples passed
Side Force	20	Withstands >4 g	All samples passed
Buckle Test	20	Baseline testing	All samples passed

Electrical performance testing was conducted on sterilized catheters 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.

ELECTRICAL PERFORMANCE TESTING

Test	Number of Devices Tested	Acceptance Criteria	Results
DC Lead Resistance			
Pre-simulated ablation #1	20	<10 Ω and within 0.4 Ω of each other	All samples passed
Pre-simulated ablation #2	20		
Pre-simulated ablation #3	20		
Post-simulated ablation #1	20		
Post-simulated ablation #2	20		
DC Isolation Resistance		Measured resistance >200 kΩ	All samples passed
Pre-simulated ablation #1	20		
Pre-simulated ablation #2	20		
Pre-simulated ablation #3	20		
Post-simulated ablation #1	20		
Post-simulated ablation #2	20		

ELECTRICAL PERFORMANCE TESTING

Test	Number of Devices Tested	Acceptance Criteria	Results
RF Lead Impedance @ 5 kHz Pre-simulated ablation Post-simulated ablation RF Lead Impedance @ 500 kHz Pre-simulated ablation Post-simulated ablation	 20 20 20 20	 Impedance <10 Ω Impedance <25 Ω	 All samples passed All samples passed
RF Isolation Impedance @ 5 kHz Pre-simulated ablation Post-simulated ablation RF Isolation Impedance @ 500 kHz Pre-simulated ablation Post-simulated ablation	 20 20 20 20	 Impedance @ 5 kHz >100 kΩ Phase angle between -86° to -90° Impedance @ 500 kHz >1 kΩ Phase angle between -86° to -90°	 All samples passed All samples passed
Temperature Reading Thermocouple Sensor Pre-simulated ablation Post-simulated ablation Thermistor Sensor Pre-simulated ablation Post-simulated ablation	 10 10 10 10	 Thermocouple thermometer reading 60 ± 2°C Thermistor resistance reading 5.80 kΩ - 6.92 kΩ at 60°C	 All samples passed All samples passed
Verify PCB Calibration	20	Calibration results read "OK"	All samples passed
Leakage Current	20	Measured RF leakage current ≤ 290 mA	All samples passed

Simulated use ablation was conducted to evaluate the functional performance of the catheter, cables, and CARTO® system. Lesion volume was measured for 10 of the 20 catheters, and was found to be comparable for all lesions and catheters.

FUNCTIONAL PERFORMANCE TESTING

Name of Test	Number of Devices Tested	Acceptance Criteria	Results
Visual Inspection Post-Ablation	20	No mechanical failures	19/20 samples passed*
Lesion Volume	10	Consistent lesions should be created for 10 catheters	Consistent lesions were produced

* One sample failed due to a break in the tip electrode leadwire.

In Vitro Location Accuracy:

Location Accuracy: Location accuracy of the CARTO® system, and ablation characteristics of the NAVI-STAR® catheter when used with the CARTO® system were assessed *in vitro* and *in vivo*. The studies found that the CARTO® system is accurate in locating the NAVI-STAR® catheter on the bench, in animals, and in humans.

Location accuracy is the difference between the actual catheter position and the CARTO® reported position. Two *in vitro* studies were conducted to evaluate the location accuracy of the CARTO® system. These studies support the claim that the CARTO® system has a location accuracy of <1mm in a static environment.

Beat-to-beat system variation, when measured in a dynamic animal model, was found to have an average maximal range and average mean error of 1.26±0.08 mm and 0.54±0.05 mm, respectively.

1.10.2 NAVI-STAR® Catheter Upper Allowable Lesion Limit

A study was conducted to evaluate an upper limit for the number of lesions that can be created using a single NAVI-STAR® catheter. All catheters were subjected to electrical testing pre- and post-ablation, with satisfactory results. Reliability testing was performed post-ablation, and all catheters met the acceptance criteria. Based on this test it was concluded the NAVI-STAR® catheter is capable of delivering RF current for 250 minutes without degradation in physical characteristics or functional performance.

1.10.3 Lesion Comparison Test for the NAVI-STAR® Catheter vs. the CELSIUS Catheter

A study was conducted to compare the lesions created with NAVI-STAR® catheters to lesions created with CELSIUS catheters. The CELSIUS catheter is a market approved catheter for the same indications for use as the NAVI-STAR® that was approved under P950005.The results demonstrated no statistically significant difference in the volume of the lesions created by the NAVI-STAR® catheter when compared to lesions created by Celsius catheter.

1.10.4 Animal Testing

Animal studies were conducted to evaluate mapping accuracy and lesion characteristics and reproducibility of the CARTO® system and NAVI-STAR® catheter.

- Beat-to-beat system variation, when measured in a dynamic animal model, was found to have an average maximal range and average mean error of 1.26±0.08 mm and 0.54±0.05 mm, respectively.
- The NAVI-STAR® catheter, when used with the CARTO® system, produces a reconstruction map that is consistent with the known anatomy and electrical activity of the pig heart.
- Studies performed in the swine RA show that the NAVI-STAR® catheter produces reconstruction of the atrium that allows accurate guidance for catheter ablation procedures: the location, shape, and continuity of the linear lesions corresponded to the autopsy findings.

The studies found that the NAVI-STAR® catheter, when used in conjunction with the CARTO® system and related accessory devices, can safely, consistently, and reliably map and ablate in the swine heart.

1.10.5 Biocompatibility Testing

The patient-contacting materials of the NAVI-STAR® catheter were tested according to ISO 10993-1:1 and ISO 10993-4. Under the ISO guidance, electrode catheters are classified as limited (<24 hour) contact duration, circulating blood, externally communicating devices. The test data established the biocompatibility of the catheter materials for the intended use.

RESULTS OF CATHETER BIOCOMPATIBILITY TESTING

Test	Results
Cytotoxicity Test Using the ISO Elution Method in the L-929 Mouse Fibroblast Cell Line	*Passed.* The MEM test extracts showed no evidence of causing cell lysis or toxicity. The negative controls, reagent controls, and the positive controls performed as anticipated. Under the conditions of this study, the MEM test extracts were not cytotoxic.
Delayed Contact Sensitization Study (A Maximization Method) in the Guinea Pig (Saline and Cottonseed Oil Extracts)	*Passed.* Under the conditions of this study, the extracts showed no evidence of causing delayed contact sensitization in the guinea pig.
Acute Intracutaneous Reactivity Study in the Rabbit (Saline and Cottonseed Oil Extracts)	*Passed.* There was no evidence of significant irritation or toxicity from the extracts injected intracutaneously into rabbits. The Primary Irritation Index for the extracts was negligible.
USP Systemic Toxicity Study in the Mouse (Saline and Cottonseed Oil Extracts)	*Passed.* There was no mortality or evidence of significant toxicity from the extracts. Each test article extract met the USP requirements.
Thromboresistance in Two Dogs (*in vivo*)	*Passed.* Under the conditions of this study, the test article exhibited minimal to no thrombus, while the control article resisted thrombogenicity.
Hemocompatibility Hemolysis *in vitro* procedure (Extraction)	*Passed.* Under the conditions of this study, the mean hemolytic index for the test article extract was 0%. The test article extract was considered to be nonhemolytic.
Rabbit Pyrogen Study – Material Mediated	*Passed.* The total rise of rabbit temperatures during the 3-hour observation period was within acceptable USP limits. The test extract was judged as nonpyrogenic.
Complement Activation Assay – ISO	*Passed.* The human plasma exposed to the test article did not exhibit increased C3a or SC5b-9 as compared to both untreated plasma and negative control plasma. The test article did not induce complement activation of C3 or C5 proteins in human plasma.

1.11 SUMMARY OF CLINICAL INVESTIGATIONS

The NAVI-STAR® Diagnostic/Ablation Catheter, when used in conjunction with the CARTO system and related accessory devices was evaluated in a clinical study with the Medtronic CardioRhythm Atakr RF generator, and the EPT RF generator for the treatment of supraventricular tachycardias.

Study Design: The NAVI-STAR® Diagnostic/Ablation Catheter was evaluated in a prospective, non-randomized, multi-center study. Acute success was defined as the inability to induce the arrhythmia for WPW and AVNRT patients, and complete heart block for AVN patients, following the ablation procedure. Chronic (3 month) success was defined as the absence of recurrence of the arrythmia over a 3 month monitoring period.

Patients Studied: Of the 320 patients enrolled, 281 patients underwent ablation and provided clinical data for the assessment of safety. For the effectiveness endpoints, the patient count included all patients treated with the NAVI-STAR® Diagnostic/Ablation Catheter, including those patients where the physician began the procedure using the NAVI-STAR® Diagnostic/Ablation Catheter and then changed to a non-protocol device to complete the procedure. The patients who began treatment with the NAVI-STAR® Diagnostic/Ablation Catheter, but were switched to a non-protocol device were considered treatment failures. Therefore, two hundred seventy-seven (277) patients were treated with the NAVI-STAR® Diagnostic/Ablation Catheter for an arrhythmia indicated in the study and were assessed for effectiveness. The other 39 patients were discontinued prior to ablation for the reasons and occurrence indicated in the table below:

Patients Discontinued Prior to Ablation

Reason for Discontinuation	Number of Patients
Physician chose not to ablate (difficult pathway, close proximity to AV node, unusual location, or other)	3
Unable to induce protocol arrhythmia	22
Non-protocol arrhythmia	14
Total number of discontinued patients:	39

Demographics: Of the 281 patients undergoing RF ablation, 158 (56%) were female and 123 (44%) were male, which is consistent with the prevalence of the disease. The mean age for all patients was 49 years (range 10-86). The distribution of supraventricular tachycardias treated is shown in the following table.

Distribution of Arrhythmias Treated

Indication	Number of patients	
	%	#
WPW	24%	69/281
AVNRT	56%	156/281
WPW/AVNRT	1%	4/281
AVNRT/other arrhythmia	2%	7/281
AV Node Ablation	14%	41/281
Non-study arrhythmia	%	4/281
All Patients	100%	281

Intraprocedural Data: For the 281 patients ablated, RF current was applied a total of 2,289 times during the study with a mean of 8.4 applications per patient (range 1-58) and a mean duration of 40.9 seconds per application (range 1-328). The mean temperature per application was 56.8°C (range 35-100°C). Mean fluoroscopy time was 20.4 minutes, and mean total procedure time was 194.5 minutes.

Acute Effectiveness: Of the 277 patients treated with the NAVI-STAR® Diagnostic/Ablation Catheter, acute success was achieved in 269 patients (97.1%). The table below summarizes acute success rates by indication and group.

Acute Procedural Success by Indication (n=277)

Indication	%	#	95% Confidence Interval
WPW	95.7%	66/69	[0.878, 0.991]
AVNRT	97.5%	159/163	[0.938, 0.993]
WPW/AVNRT	100%	4/4	[0.398, 1]
AVNRT/supplemental arrhythmia*	100%	4/4*	[0.398, 1]
AV Node Ablation	97.6%	40/41	[0.871, 0.999]
All Patients	97.1%	269/277	[0.944, 0.987]

* Not counted in total

Chronic Effectiveness: Of the 198 patients available for 3-month follow-up, chronic success was achieved in 185 (93.4%). Six-month chronic success was reported for 159

(95.7%) of 166 core patients available for follow-up. The tables below summarize chronic success rates by indication and group.

95% confidence interval Chronic Success by Indication at 3 Months

Indication	3 Months		95% Confidence Interval	
	%	#	Lower Limit	Upper Limit
WPW	95.3%	41/43	0.842	0.994
AVNRT	93.0%	107/116	0.858	0.964
WPW/AVNRT	100%	4/4	0.398	1.000
AVNRT/other arrhythmia	100%	5/5	0.478	1.000
AV Node Ablation	93.1%	27/29	0.772	0.992
AV Node Ablation & Other	100%	1/1	0.025	1.000
All Patients	93.4%	185/198	0.890	0.965

95% confidence interval Chronic Success by Indication at 6 Months

Indication	6 Months		95% Confidence Interval	
	%	#	Lower Limit	Upper Limit
WPW	91.2%	31/34	0.763	0.981
AVNRT	94.7%	89/94	0.880	0.983
WPW/AVNRT	100%	3/3	0.292	1.000
AVNRT/other arrhythmia	100%	2/2	0.158	1.000
AV Node Ablation	100%	25/25	0.863	1.000
AV Node Ablation & Other	100%	1/1	0.025	1.000
All Patients	95.0%	151/159	0.903	0.978

In separate clinical studies for a PMA approved ablation catheter (CELSIUS® P95005), Biosense Webster collected the clinical data shown in the table below.

Device Performance Compared to Control Group

Study Endpoint	NAVI-STAR® Catheter	Control	Exact One-Sided 95% Confidence Bound
Acute Success	97.1%	92.1%	93.9%
Chronic Success	93.4%	91.5%	88.4%
Major Complications	1.8%	3.5%	4.4%

The safety, acute effectiveness, and chronic effectiveness results from the NAVI-STAR® Diagnostic/Ablation Catheter study were demonstrated to be statistically equivalent to the control data.

1.12 CONCLUSIONS DRAWN FROM THE STUDIES

Preclinical testing demonstrates that the NAVI-STAR® Diagnostic/Ablation catheter should maintain its mechanical and electrical integrity, and that the patient contacting materials should be biocompatible under the proposed conditions of use. The bench testing established an appropriate degree of localization accuracy.

Clinical data submitted under P990025 provide reasonable assurance that the NAVI-STAR® Diagnostic/Ablation catheter is reasonably safe and effective for the stated indications under the proposed conditions of use.

1.13 PANEL RECOMMENDATION

Pursuant to the provision 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, and FDA Advisory Panel Committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this Panel.

1.14 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, P990025, on

JUN 15 2000

1.15 APPROVAL SPECIFICATION

- Directions for Use: See final approved labeling (Instructions for Use)
- Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings and Precautions, and Adverse Events in the final approved labeling (Instructions for Use)
- Post-Approval Requirements and Restrictions: See Approval Order.