

**DE NOVO CLASSIFICATION REQUEST FOR
AMIGO REMOTE CATHETER SYSTEM**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Steerable Cardiac Ablation Catheter Remote Control System. A Steerable Cardiac Ablation Catheter Remote Control System is a prescription device that is external to the body and interacts with the manual handle of a steerable cardiac ablation catheter to remotely control the advancement, retraction, rotation, and deflection of a compatible, steerable ablation catheter used for the treatment of cardiac arrhythmias in the right side of the heart. The device allows reversion to manual control of the steerable cardiac ablation catheter without withdrawal of the catheter and interruption of the procedure.

NEW REGULATION NUMBER: 21 CRF 870.5700

CLASSIFICATION: CLASS II

PRODUCT CODE: PJB

BACKGROUND

DEVICE NAME: AMIGO REMOTE CATHETER SYSTEM

SUBMISSION NUMBER: DEN140009

DATE OF DE NOVO: FEBRUARY 18, 2014

**CONTACT: CATHETER ROBOTICS, INC.,
500 INTERNATIONAL DRIVE
MOUNT OLIVE, NJ 07828**

REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS II

INDICATIONS FOR USE

The Amigo™ Remote Catheter System (RCS) is intended to facilitate manipulation, positioning and control of compatible percutaneous electrophysiological ablation catheters that deliver RF energy in the right atrium. Use of Amigo RCS should also be in accordance with the indications for use of compatible ablation catheters. The Amigo RCS should only be used with the Boston Scientific catheters (with the Blazer™ handle) and/or the Biosense Webster catheters (with the EZ Steer® handle) in the right atrium.

LIMITATIONS

For prescription use only.

Do not use in patients who are contraindicated for cardiac catheterization procedures.

Safety and effectiveness of Amigo RCS for the control of ablation catheters in other chambers of the heart not included in the Indications for Use have not been established.

The Amigo RCS is currently designed for use with ONLY the compatible EP catheters listed in the Compatible Catheters and Mechanical Testing Summary Section of the Instructions for Use; do not use with any other EP catheters. The safety and effectiveness of this device for cardiac ablation in the right atrium when used with any ablation catheter other than the Boston Scientific catheters (with the Blazer™ handle) and/or the Biosense Webster catheters (with the EZ Steer® handle) has not been established.

Note: Blazer is a trademark of Boston Scientific Corporation. EZ STEER is a registered trademark of Biosense Webster, Inc.

Amigo is not to be used to manipulate a catheter except under visualization with fluoroscopy.

For either docking station, catheters that are larger than 8.5 Fr are not compatible with Amigo RCS as they will not fit through the spreader.

During manipulation of the catheter with Amigo RCS, the physician will not receive any tactile feedback from the catheter. Care should be taken not to advance the catheter against the side wall of the vessel or heart with excess force. Damage or perforation of the wall may result.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Amigo™ Remote Catheter System (Amigo RCS) is designed to facilitate the manipulation, positioning and control of compatible cardiac electrophysiological catheters. It is designed to remotely control Boston Scientific catheters (with the Blazer™ handle) and Biosense Webster catheters (with the EZ STEER® handle).

(Note: Blazer is a trademark of Boston Scientific Corporation. EZ STEER is a registered trademark of Biosense Webster, Inc.)

The Amigo RCS consists of four (4) main reusable, non-sterile components including the remote catheter system (sled, track, and turret), a hard-wired remote control, 100 ft extension cable, and a bridge support with rail and frame. In addition, the Amigo RCS includes three (3) sterile, single-use disposable kits including the docking station kit (docking station and spreader) to

interface with the compatible ablation catheter, and a sterile cover kit (sled cover, turret cover, nose sleeve and side covers) and track kit (track and nosecone) used to maintain a sterile field during device use. The Amigo RCS is intended to attach to the rails of an IEC 60601-1 compliant EP bed system. Please refer to Figures 1 and 2 below, as well as the device's Instructions for Use and accompanying User Manual for additional details.

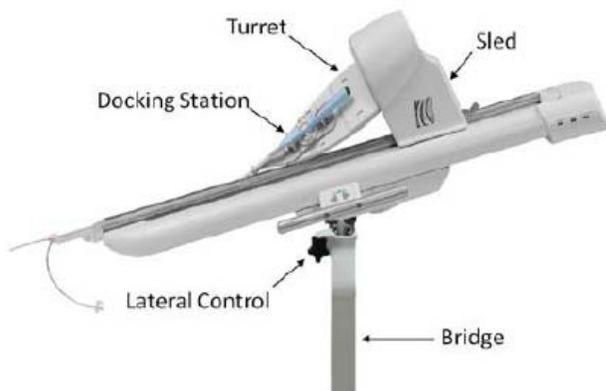


Figure 1: Amigo® Catheter Controller Platform with Docking Station.



Figure 2: Remote Control Unit

The Amigo RCS only interfaces with the catheter's handle such that the Amigo RCS connects to and operates the manual handle of the compatible steerable cardiac ablation catheter to remotely control its advancement, retraction, rotation, and deflection. As shown in Figure 1, the handle is placed in the corresponding docking station, which in turn is locked into the turret. The sled portion of Amigo provides insertion and withdrawal positioning. The turret portion of Amigo provides rotational positioning / orientation of the catheter. The turret also contains the drive mechanism for the catheter deflection control. The deflection control driveshaft protrudes from the flat side of the turret. The deflection driveshaft interfaces with the deflection knob located on the docking station to move the deflection lever.

The remote control unit (Figure 2) is modeled after existing, commercially available catheter handles. The remote controller allows the physician to remotely maneuver the catheter position (insertion, withdrawal, rotation) and tip deflection (bend) from up to 100 feet away. The remote control unit is electronically linked via a 100 ft long extension cable to the catheter controller platform (docking station). The remote controller also includes an infrared light beam lockout system. This is intended to prevent unintentional operation of the controller. The remote controller can only be operated when the infrared light beam (located on the controller body) is interrupted by being held and covered by the operator's hand. Holding the controller in the hand allows normal operation. The remote controller is disabled when it is not held in the operator's hand.

When using the Amigo RCS, physicians use standard fluoroscopy to visualize the movement and placement of the catheter in the same way they would for a manual catheter procedure. Therefore, the Amigo RCS is an optional and ancillary accessory to the cardiac catheter, and it does not provide any diagnostic or visual information or therapy by itself. The remote control

option allows the physician the choice to be positioned outside of the fluoroscopy radiation field during the catheter procedure.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

There are no patient-contacting materials for the subject device. For this reason, biocompatibility testing is not required.

SHELF LIFE/STERILITY

The Amigo RCS is provided non-sterile as it is intended for external use, but does include sterile components, including a disposable sterile cover kit, which are used to cover components of the system within the sterile field. For the non-sterile system, the Amigo RCS user manual includes appropriate cleaning instructions for the external surface of the device. The device does not have a stated shelf life, which based upon the nature of the device components is acceptable. The additional sterile components underwent shelf-life/packaging and sterilization testing in accordance with the following standards: b(4)

All sterilization and packaging testing resulted in a PASS, and each component was validated for a shelf life of 3-years. This is incorporated into each components corresponding manual and package label.

The single-use components of Amigo (docking station, track, spreader, nosecone and sterile covers) are to be disposed of as biohazard waste. Post-procedure, the ablation catheter is considered a biohazard and disposed in accordance with the catheter manufacturer's Instructions for Use and disposal instructions.

The user manual also includes instructions for cleaning of the reusable components (Amigo RCS, bridge support with rail and frame, controller, and extension cable). The instructions state that these components should be wiped down after patient use with standard medical cleaning agents available in the hospital.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The device was tested in accordance with the following FDA recognized consensus standards for electromagnetic compatibility and electrical safety:

Standard	Title
IEC 60601-1: 2007	Medical electrical equipment – Part 1: General requirements for safety and essential performance.
IEC 60601-1-2: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Additionally, the Amigo RCS electrical performance when used with the compatible ablation catheters was evaluated in an animal study. The study demonstrated that the

Amigo RCS does not impact catheter function and performance (all ranges of motion of catheter, tip deflection, and mapping). The results from the animal study also evaluated the accuracy and function of all device electrical controls for proper tip placement within the chambers of the heart.

SOFTWARE

There is no software incorporated into the Amigo RCS control system.

PERFORMANCE TESTING – MECHANICAL TESTING

Mechanical testing compared manual versus remote control manipulation using the Amigo RCS for each catheter handle family (Blazer™ and EZSteer®). The mechanical testing included evaluation of the following acceptance criteria: (1) Ability to attach catheter handle and maintain mechanical attachment to docking station; (2) Deflection of the catheter with Amigo RCS is equivalent to manual deflection (less than or equal to 1° difference in catheter handle throw) over the range of functional clinical application; (3) Catheter and spreader remains in the track and the catheter extends, retracts, and rotates in both directions through the spreader and articulates correctly; (4) Improper configuration of Amigo RCS/docking station does not result in overstressing the catheter.

Additionally, the Amigo RCS mechanical performance was evaluated in an animal study for simulated use and placement of the compatible catheter within the chambers of the heart, including the right atrium. The study demonstrated that the Amigo RCS does not impact catheter function and performance (all ranges of motion of catheter, tip deflection, and mapping). The results from the animal study also evaluated the accuracy and function of all device mechanical controls for proper tip placement within the chambers of the heart.

SUMMARY OF CLINICAL INFORMATION

Data from three clinical studies involving 85 patients who underwent Amigo RCS-controlled catheter ablation demonstrated the safety and effectiveness of the device for use in the right atrium.

Study Design:

All three studies were prospective cohort studies. Of the three studies, one study was a 3-center study, while the other two were single-center studies. Collectively, the studies used the Amigo RCS with compatible Blazer™ or EZSteer® catheters. Evaluation of adverse events for safety, and acute procedural success was the primary effectiveness measurement in all three studies. Chronic success and procedural parameters (procedural time, total fluoroscopy time, operator fluoroscopy time) were the secondary effectiveness measurements. For two of the studies, chronic success was defined as absence of arrhythmia recurrence at 6 months post ablation for a total of 72 patients with atrial flutter and 5 patients with AVNRT, and in a third study, it was defined as absence of arrhythmia recurrence at 12 months for 8 atrial flutter patients) and procedural parameters. In one study with a matched control group, the procedural time and total fluoroscopy time of the Amigo RCS procedures were comparable to manual ablation.

Population:

Patients indicated for arrhythmia ablation procedures in the right atrium.

Results:

Acute procedural success was achieved in 84/85 (98.8%) subjects who underwent catheter ablation using Amigo RCS to control a RF ablation catheter for the treatment of typical atrial flutter (AFL) (n = 80) or atrioventricular nodal reentrant tachycardia (AVNRT) (n = 5). Acute procedural success was not obtained in one AFL patient when using Amigo RCS to control a RF ablation catheter.

Chronic success was achieved in 62/63 (98.4%) of subjects who completed the predefined follow-up period at the time of the reports.

Operator fluoroscopy time was decreased by 71% for typical AFL ablation and by 81% for AVNRT ablation by using Amigo RCS compared with manual ablation.

Adverse Events:

Results from the three clinical studies suggested that the rates of adverse events (AEs) associated with Amigo RCS-controlled ablation were comparable to those associated with manual ablation. There were no device-related, serious AEs reported in the three studies. The complication rate for the most common right atrial ablation procedures (e.g. typical atrial flutter ablation) was about 3%. Procedure-related major vascular access complication occurred in 1/85, or 1.2% of subjects from the three studies. Minor vascular access complication occurred in 2/85, or 2.4% of subjects from the three studies.

TRAINING PROGRAM:

Instructions for proper personnel training are included in the instructions for use/user manual for Amigo RCS. This training program was developed based on the training implemented, and operator performance observed, during the clinical studies mentioned above.

POST-MARKET SURVEILLANCE:

The FDA is requiring Catheter Robotics, Inc., the manufacturer of the Amigo RCS, to complete post-market surveillance to collect additional adverse event data for common procedures included within the indications for use in the right atrium, and to inform user training and labeling. The sponsor has agreed to conduct post-market surveillance based on an agreed-upon protocol between the sponsor and FDA.

LABELING

The Amigo RCS user manuals are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact use of the device. Proper instructions for training are also included. The labeling is sufficient and satisfies the requirements of 21 CFR § 801.109 Prescription devices. In addition, the labeling also complies with special controls to include dedicated sections for a description of compatible catheters and a summary of tests used to evaluate compatibility (description of compatible catheters for each of the docking stations, device technical parameters, mechanical testing summary, *in vivo* studies summary (i.e., animal or clinical studies), and any labeling updates resulting from the post-market surveillance). Inclusion of reference to specific PMA approved ablation catheters in the Amigo RCS labeling

was acceptable in this circumstance because Amigo RCS is optional and ancillary to the PMA device/system, and the Amigo RCS system does not replace or modify any part or component of the approved PMA device, nor change its principles of operation.

RISKS TO HEALTH

Table 1 below identifies the risks to health that may be associated with use of Steerable Cardiac Ablation Catheter Remote Control Systems and the measures necessary to mitigate these risks.

Table 1: Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Device failure, resulting in patient injury or interruption of procedure	<ul style="list-style-type: none"> • Non-clinical Mechanical Performance testing • Non-clinical Electrical testing: Electromagnetic Compatibility (EMC), Electrical Safety, Electrical System Performance • Shelf-life Testing • Sterilization Testing • <i>In vivo</i> Testing • Labeling • Training
Device alters catheter functionality (advance/withdrawal, rotation, deflection) resulting in patient injury (e.g., perforation) or improper catheter performance (positioning and contact) or interruption of procedure	<ul style="list-style-type: none"> • Non-clinical Mechanical Performance testing • Non-clinical Electrical testing: Electromagnetic Compatibility (EMC), Electrical Safety, Electrical System Performance • <i>In vivo</i> Testing • Labeling • Post Market Surveillance
Adverse Tissue Reaction	<ul style="list-style-type: none"> • Sterilization Testing
Improper device use/Use Error	<ul style="list-style-type: none"> • Labeling • Training • <i>In vivo</i> Testing • Post Market Surveillance
Interference with Other Electrical Equipment/Devices (e.g., device malfunction)	<ul style="list-style-type: none"> • Non-clinical Mechanical Performance testing • Non-clinical Electrical testing: Electromagnetic Compatibility (EMC), Electrical Safety, Electrical System Performance

Identified Risk	Mitigation Measure
Electrical Shock	<ul style="list-style-type: none"> • Labeling • Non-clinical Electrical testing: Electrical Safety testing • Labeling
Device Malfunction resulting in Unanticipated Operation (e.g., Device Stoppage, Unintended Movement)	<ul style="list-style-type: none"> • Non-clinical Mechanical Performance testing • Non-clinical Electrical testing: Electromagnetic Compatibility (EMC), Electrical Safety, Electrical System Performance • <i>In vivo</i> Testing • Labeling • Training

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the Steerable Cardiac Ablation Catheter Remote Control System is subject to the following special controls:

1. Non-clinical mechanical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be performed:
 - Mechanical performance of the system (without catheter connected)
 - Mechanical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following:
 - Side-by-side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions
 - Evaluation of the accuracy and function of all device control safety features
 - Simulated-use testing in a bench anatomic model or animal model

2. Non-clinical electrical testing must include validation of electromagnetic compatibility (EMC), electrical safety, thermal safety, and electrical system performance. The following performance testing must be performed:
 - Electrical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following:

- Side-by side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions
 - Evaluation of the accuracy and function of all device control safety features
 - Electrical safety between the device and ablation catheter system and with other electrical equipment expected in the catheter lab or operating room.
3. *In vivo* Testing must demonstrate that the device performs as intended under anticipated conditions of use, including an assessment of the system impact on the functionality and performance of compatible catheters, and documentation of the adverse event profile associated with clinical use. Evidence must be submitted to address the following:
- Manipulation and Positioning: Ability to manipulate compatible catheters to pre-specified cardiac locations and confirm proper anatomic placement and tissue contact; in accordance with the system indications for use and the compatible catheter indications for use.
 - Safety: Assess device-related complication rate and major procedural complication rate (regardless of device relatedness) in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use.
 - Efficacy: Assess ablation success in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use.
 - User assessment of device remote controls and safety features
4. Post-market surveillance (PMS) must be conducted and completed in accordance with FDA-agreed upon PMS protocol.
5. A training program must be included with sufficient educational elements that upon completion of the training program, the clinician and supporting staff can:
- Identify the safe environments for device use
 - Use all safety features of device
 - Operate the device in simulated or actual use environments representative of indicated environments and use for the indication of compatible catheters.
6. Performance data must demonstrate the sterility of the sterile disposable components of the system.

7. Performance data must support shelf life by demonstrating continued sterility of the device (of the sterile disposable components), package integrity and device functionality over the requested shelf life.

8. Labeling must include the following:
 - Appropriate instructions, warnings, cautions, limitations, and information related to the intended patient population, compatible ablation catheters, and the device safeguards for the safe use of the device.
 - Specific instructions and the clinical training needed for the safe use of the device, which includes:
 - instructions on assembling the device in all available configurations, including installation and removal of compatible catheters
 - instructions and explanation of all controls, inputs, and outputs,
 - instructions on all available modes or states of the device,
 - instructions on all safety features of the device, and
 - validated methods and instructions for reprocessing/disinfecting any reusable components
 - A detailed summary of the mechanical compatibility testing including:
 - A table with a complete list of compatible catheters tested (manufacturer trade name and model number)
 - A table with detailed test results, including type of test, acceptance criteria and test results (i.e., pass for meeting acceptance criteria)
 - A detailed summary of the *in vivo* testing including:
 - A table with a complete list of compatible catheters used during testing (manufacturer trade name and model number)
 - Adverse events encountered pertinent to use of the device under use conditions
 - A detailed summary of the device- and procedure-related complications
 - A summary of study outcomes and endpoints. Information pertinent to the fluoroscopy times/exposure for the procedure, patient and operator fluoroscopic exposure
 - Other labeling items
 - A detailed summary of pertinent non-clinical testing information: EMC, mechanical, electrical, and sterilization of device and components
 - A detailed summary of the device technical parameters
 - An expiration date/shelf life and storage conditions for the sterile accessories
 - When available, and according to the timeframe included in the PMS protocol agreed upon with FDA, provide a detailed summary of the Post-Market Surveillance (PMS) data including:

- Updates to the labeling to accurately reflect outcomes or necessary modifications based upon data collected during the PMS experience
- Inclusion of results and AEs associated with utilization of the device during the PMS

BENEFIT/RISK DETERMINATION

The evaluation of risks of the device is based on data collected in the clinical studies described above. No serious device-related adverse events were reported in the clinical performance data for use of the device in the right atrium. Procedure-related adverse events (vascular access complications including both major and minor adverse events) were observed in 3.6% of the study subjects. Based on this information, the risk associated with this device is considered acceptable.

The probable benefits of the device are also based on data collected in clinical studies as described above. The results from the clinical studies showed that Amigo RCS-controlled right atrial ablation yielded very high acute and chronic ablation success rates, which were comparable to conventional manual ablation. The results also demonstrated that the procedure time and total fluoroscopy time were also similar between Amigo RCS-controlled ablation and conventional ablation for the patient; however, there was a 70% reduction in the operator's fluoroscopy exposure time. Therefore, the data supports that Amigo RCS-controlled right atrial ablation provides the same benefit (i.e., prevention of arrhythmia recurrence) to patients as conventional ablation, while also providing a significant reduction in operator radiation exposure.

Additional factors to be considered in determining probable risks and benefits for the Amigo RCS include: (1) there were several limitations in the clinical studies that raised issues of uncertainties regarding device effectiveness and safety for the right atrial indication. This included limited study design elements (e.g., small sample size, single center, etc.) and limited rigor in adverse event detection, documentation and adjudication. (2) However, these uncertainties were considered acceptable because (2a) the majority of the study patients underwent Amigo RCS-controlled ablation for typical atrial flutter (AFL), a matured but most complex right atrial ablation procedure. The success rate in these patients with typical AFL was approaching 100%. This significantly reduces the uncertainties surrounding device effectiveness in typical AFL ablation and other underrepresented right atrial ablation procedures; (2b) the adverse events (AEs) related to the device use in right atrial ablation (e.g., perforation) are expected to manifest prior to hospital discharge when patients are closely monitored. This reduces the uncertainties surrounding AE assessment. The fact that no device related AEs were reported in any of study subjects and the procedure related major complication rate was 1.2% suggests that the risk associated with the Amigo RCS-controlled ablation procedure in the right atrium is low; (2c) the probability of Amigo RCS-controlled right atrial ablation being associated with a greater risk than conventional ablation is expected to be low due to several safety features of the device; (2d) Absence of tactile feedback from the human operator is a primary difference between Amigo RCS-controlled catheter ablation and manual ablation. There is no conclusive data that has demonstrated that tactile feedback is critical for ablation success and avoiding complications. The favorable results from the clinical studies seem to suggest that tactile feedback is not critical in a right atrial ablation procedure. (3) In addition, given the

limitations in the studies, a post market surveillance study to provide confirmatory data for the device use in other common right atrial ablation procedures, especially in AVNRT ablation, is a required special control for this de novo.

Given the totality of nonclinical and clinical data, the submitted information provides reasonable assurance that the device performs its intended function correctly and safely and does not alter the safety and effectiveness profiles of the approved catheters for the treatment of arrhythmias in the right atrium. Similar to conventional right atrial ablation, the benefit of preventing arrhythmia recurrence from Amigo RCS-controlled catheter ablation outweigh the risks associated with the procedure. Although the studies did not show any “add-on” benefits to patients from the use of Amigo RCS vs. manual ablation, the benefit of fluoroscopy time reduction to the physicians was demonstrated. The device risks can be mitigated by the use of general and the identified special controls, including a Post Market Surveillance (PMS) study to provide confirmatory data for the device use in common right atrial ablation procedures, especially in AVNRT ablation, and to inform labeling and training.

CONCLUSION

The *de novo* for the Amigo RCS is granted and the device is classified under the following:

Product Code: PJB

Device Type: Steerable Cardiac Ablation Catheter Remote Control System

Class: Class II

Regulation: 21 CFR 870.5700