



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2014

Catheter Robotics, Inc.
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Re: DEN140009 - K140394
Amigo® Remote Catheter System (Amigo RCS)
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 870.5700
Regulation Name: Steerable Cardiac Ablation Catheter Remote Control System
Regulatory Classification: Class II
Product Code: PJB
Dated: February 14, 2014
Received: February 18, 2014

Dear Ms. Englund:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Amigo® Remote Catheter System (Amigo RCS), a prescription device under 21 CFR Part 801.109 that is indicated 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.* FDA concludes that this device should be classified into class II. This order, therefore, classifies the Amigo® Remote Catheter System (Amigo RCS), and substantially equivalent devices of this generic type, into class II under the generic name, Steerable Cardiac Ablation Catheter Remote Control System.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On February 18, 2014, FDA received your *de novo* requesting classification of the Amigo® Remote Catheter System (Amigo RCS) into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Amigo® Remote Catheter System (Amigo RCS) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Amigo® Remote Catheter System (Amigo RCS) indicated “*to facilitate manipulation, positioning and control of compatible percutaneous electrophysiological ablation catheters that deliver RF energy for treatment of cardiac arrhythmias 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*”, can be classified in class II with the establishment of special controls for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

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

Identified Risk	Mitigation Measure
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 • Labeling
Electrical Shock	<ul style="list-style-type: none"> • 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

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:
 - a. Mechanical performance of the system (without catheter connected)

- b. 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:
 - i. 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
 - ii. Evaluation of the accuracy and function of all device control safety features
 - c. 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:
 - a. 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:
 - i. 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
 - ii. Evaluation of the accuracy and function of all device control safety features
 - b. 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:
 - a. 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.
 - b. 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.
 - c. Efficacy: Assess ablation success in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use.
 - d. 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:
 - a. Identify the safe environments for device use
 - b. Use all safety features of device
 - c. 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:
 - a. 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.
 - b. Specific instructions and the clinical training needed for the safe use of the device, which includes:
 - i. instructions on assembling the device in all available configurations, including installation and removal of compatible catheters
 - ii. instructions and explanation of all controls, inputs, and outputs,
 - iii. instructions on all available modes or states of the device,
 - iv. instructions on all safety features of the device, and
 - v. validated methods and instructions for reprocessing/disinfecting any reusable components
 - c. A detailed summary of the mechanical compatibility testing including:
 - i. A table with a complete list of compatible catheters tested (manufacturer trade name and model number)
 - ii. A table with detailed test results, including type of test, acceptance criteria and test results (i.e., pass for meeting acceptance criteria)
 - d. A detailed summary of the *in vivo* testing including:
 - i. A table with a complete list of compatible catheters used during testing (manufacturer trade name and model number)
 - ii. Adverse events encountered pertinent to use of the device under use conditions
 - iii. A detailed summary of the device- and procedure-related complications
 - iv. A summary of study outcomes and endpoints. Information pertinent to the fluoroscopy times/exposure for the procedure, patient and operator fluoroscopic exposure
 - e. Other labeling items
 - i. A detailed summary of pertinent non-clinical testing information: EMC, mechanical, electrical, and sterilization of device and components
 - ii. A detailed summary of the device technical parameters
 - iii. An expiration date/shelf life and storage conditions for the sterile accessories

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

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Steerable Cardiac Ablation Catheter Remote Control System they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Deborah Castillo, Ph.D., at deborah.castillo@fda.hhs.gov or by phone at (301) 796-4908.

Sincerely yours,

Jonette R. Foy -S

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