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DRAFT VERSION

CARDIAC ABLATION PRELIMINARY GUIDANCE

Data to be Submitted to the Food and Drug Administration in
Support of Investigational Device Exemption Applications

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Introduction

Ablation is accomplished by thermal destruction of endocardial tissue due to resistive heating at the site of the tip electrode of the ablation catheter. Catheter delivery systems that are intended to be used to deliver energy to cardiac tissue in the treatment of arrhythmias have been classified as class III devices, and require approval of a Premarket Approval (PMA) application in order to be legally marketed in the United States. This preliminary guidance was developed in order to provide a description of the type of information that the Food and Drug Administration (FDA) anticipates to support the use of these devices in clinical investigations. The guidance should supplement the information that is required under section 520(g) of the Federal Food, Drug, and Cosmetic Act and part 812, of Title 21 of the Code of Federal Regulations (CFR). Questions may be directed to the Pacing and Neurological Devices Branch at (301) 443-8517.

Intended Uses

These devices are used to locate sites in the heart and ablate regions of endocardial tissue that give rise to, or support, cardiac arrhythmia. The sites are located by mapping the electrical signals of the heart. Indications for use may include: interruption of atrioventricular (AV) conduction pathways associated with tachycardia; treatment of AV nodal reentrant tachycardia; creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia; treatment of atrial flutter/fibrillation; and, treatment of ectopic atrial tachycardia. (Note that treatment of ventricular tachycardia will be amended to this guidance in the future or be covered under a separate document.)

Labeling Requirements

Submit copies of all proposed labels, and labeling that are sufficient to describe the device, its intended use, and the directions for use. The labeling must bear the statement: "Caution-Investigational Device. Limited by Federal (or United States) law to investigational use.", and include indications, contraindications, warnings, and precautions.

Device Description

See Electrode Recording Catheter Preliminary Guidance.

Biocompatibility

See Electrode Recording Catheter Preliminary Guidance.

Sterility

See Electrode Recording Catheter Preliminary Guidance.

Performance Testing

The performance tests listed in the Electrode Recording Catheter Preliminary Guidance have been outlined below, all tests listed below are also required for Cardiac Ablation Catheters. The tests which are identified with an asterisk are not required for IDE approval but are necessary upon PMA submission.

I. Performance Testing

A. Reliability Testing

1. Thermal Cycling
 2. Tensile Testing
 3. Torsional Testing
 4. Joint Seal
 5. Leakage Current
 6. Deflection Fatigue
 7. Flexion Fatigue
 - * 8. Connector
 - * 9. Accessory Cable Fatigue
- a. Open Lumen Catheters
 - i. Stylet Forces
 - ii. Infusion
 - iii. Leak
 - iv. Response

B. Materials and Mechanical Testing

- * 1. Torsion
- * 2. Deflection
3. Steering
- * 4. Bending
5. Buckling Force
6. Radiopacity

C. Electrical Testing

1. Impedance
2. Noise
3. Stimulation
- * 4. Mapping

In addition to testing listed above the following Performance Testing should also be performed.

Reliability Testing

1. Design a catheter reliability test that simulates the actual use of the device and involves thermal cycling in a biological medium as well as current delivery. This information will be used to support the recommended number of energy deliveries per catheter in the labeling, and should include assessment of the electrode-tubing joint integrity, mechanically and microscopically, as well as a determination of the impact of multiple applications of RF energy on the composition of the materials.

Electrical Testing

1. Determine the impedance at the frequencies supplied by the power generator.
2. Determine the high frequency leakage current in the catheters and cable according to ANSI/AAMI HF18, or an equivalent, and the extent of conductor-to-conductor coupling which could result in power delivery to the band electrodes according to IEC 601-2-2.

Quality Assurance

See Electrode Recording Catheter Preliminary Guidance.

BASIC STUDY DESIGN

The following items are intended to guide prospective sponsors in the design of clinical studies of radio frequency catheter ablation studies for the treatment of supraventricular tachycardia.

1. The patient selection criteria should exclude patients with a prior acute ablation failure within two (2) months of enrollment into your study, and exclude asymptomatic

patients who are not refractory to, or intolerant of, at least one antiarrhythmic drug. Patients with retrograde accessory pathway conduction, atrioventricular junctional re-entrant tachycardia, atrial flutter, and atrial tachycardia should have frequent symptomatic episodes of their arrhythmia (e.g., >1 episode per month). Include failure to obtain informed consent or comply with the follow-up requirements as an exclusion criteria. Investigators should document the reasons for lack of participation in patients who otherwise meet the inclusion criteria.

2. Document the type, frequency, and severity of arrhythmia symptoms, prescribed medications, reasons for the medication and any known antiarrhythmic effect of the drug, and hospitalizations or emergency department visits during the six (6) month period prior to enrollment into your study.
3. The follow-up schedule should be adequate to capture patients with infrequent episodes of their dysrhythmia. The follow-up schedule that we recommend includes office visits at 1, 3, 6, 12, and 24 months. (Note that further follow-up may be a condition of approval of your PMA.) During these visits you should collect the following patient data: the type, frequency, and severity of arrhythmia symptoms; number of days post ablation when the symptoms developed; prescribed medications, reasons for the medication and any known antiarrhythmic effect of the drug; and, hospitalizations or emergency department visits since the last follow-up evaluation. You should also obtain a 12-lead electrocardiogram during each visit, and the physical examination should include examination for skin injury due to radiation exposure.
4. Document the results of electrophysiology studies in patients who complain of symptoms of their arrhythmia during the follow-up period or provide other objective evidence to verify that those symptoms are not related to cardiac dysrhythmia.
5. We have also requested monitoring of creatine phosphokinase concentration (total and myocardial band), or other enzymatic indicator of myocardial damage. Propose a schedule of this blood work that includes a pre-ablation baseline measurement and regular postablation measurements. We recommend that the analysis be performed by a core laboratory.
6. We recommend that pre- and postablation echocardiograms be evaluated by a core laboratory, in which observers are blinded to the pre- and postablation records.
7. Record typical x-ray tube voltage and current during the

mapping and ablation portion of the procedure.

8. Provide investigators with a guideline for the electrophysiologic criteria to be used in the selection of the ablation site, and for the energy delivery protocol (recommended initial power or temperature setting and duration) for each indication, as part of your investigational plan.
9. Record target and actual ablation temperature or power, or both, in the patient data forms.
10. Record whether AV junctional re-entrant tachycardia is treated by fast or slow pathway ablation, the tachycardia is common or uncommon form, and consider assessment of AV node conduction and refractoriness pre- and post ablation.
11. For each automatic shut-off of the generator, you should record the mode of the shut-off, whether the catheter was removed and cleaned, and whether the tip electrode was coated with coagulum.
12. We believe that acute safety and effectiveness data (echocardiogram, enzymes, and outcomes) should be obtained for patients who are subjected to ablation attempts with the investigational catheters but are ultimately treated with a non-investigational device.