

DRAFT FDA Questions for the Circulatory System Devices Panel

March 6, 2003

P020045

CryoCath Technologies, Inc. 7F Freezor Cardiac Cryoablation Catheter and CCT.2 Cryoablation Console System

Results of this clinical trial were compared to objective performance criteria (OPCs) established for the study for both safety and effectiveness. The OPCs were determined from the radiofrequency ablation medical literature.

Safety

1. The safety endpoint was the occurrence of major complications, as defined in the study protocol. The FDA interprets the definition of major complications to include all adverse events requiring treatment which occurred within 7 days of the procedure. The upper 95% confidence bound for the major complication rate was 8.5%. This exceeded the safety OPC, which specified an upper 95% confidence bound of less than 7%. Please comment on the following:
 - a. Please discuss whether the results of the clinical study provide a reasonable assurance of device safety for the intended patient population.
 - b. Please discuss the applicability of a safety OPC for cryoablation which was based on reported clinical experience with radiofrequency ablation.

Effectiveness - Ablation

2. The device did not meet the effectiveness OPC for the overall study population or for any patient subgroup. The lower 95% confidence bound for acute success for the entire study population was 76%. The OPC for acute success specified a lower 95% confidence bound > 85%.
 - a. Please discuss whether the results of the clinical study provide a reasonable assurance of effectiveness in (a) the overall patient population or (b) in any individual patient subgroup.
 - b. If the clinical trial does not provide enough evidence of effectiveness please discuss what would be needed.

Effectiveness - Cryomapping

3. The submission describes the use of cryomapping technology and effectiveness evaluation. Please discuss whether the study results show that the cryomapping technology is effective for use in the intended patient population.

Training/Learning Curve

4. Acute success rate varied per institution in this study. Acute success rate per institution ranged between 0 and 100%.
 - a. Please discuss the concept of site-based and physician-based learning curves.
 - b. All new devices inherently involve a learning curve in their evaluation. Please discuss whether the concept of a learning curve, either per site or per physician, may be considered in the evaluation of device safety and effectiveness.
 - c. Please discuss whether and/or what type of physician training should be required for this device if approved.

Labeling

5. Labeling for a new device should indicate which patients are appropriate for treatment, should identify potential device-related adverse events, and should explain how the device should be used to optimize its risk/benefit profile. If you recommend device approval, please address the following:
 - a. Please discuss whether the proposed warnings, precautions, and contraindications are acceptable, based on the study results.
 - b. Please discuss whether the instructions for use adequately describe how the device should be used.

Post-Market Study

6. If you recommend approval, please discuss whether a post-market study should be performed to address any issues that are unresolved, but not essential to the premarket approval of the device.