



Brief Summary of the Circulatory System Devices Panel Meeting – December 8, 2011

Introduction:

The Circulatory System Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on December 8, 2011 to discuss, make recommendations, and vote on information related to the PMA P100045 for CardioMEMS *Champion*[™] HF Monitoring System for Patients with NYHA Class III Heart Failure.

The portion of the sponsor's approved Indications for Use statement that is relevant to this product is the following:

The Champion HF Monitoring System is indicated for wirelessly measuring and monitoring PA pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and to reduce heart failure hospitalizations.

The Champion HF Monitoring System is used by the physician in the hospital or office setting to obtain and review PA Pressure Measurements. The Champion HF Monitoring System is used by the patient in the home or other remote location to wirelessly obtain and send hemodynamic and PA pressure measurements to a secure database for review and evaluation by the patient's physician.

Vote:

The following questions were posed to the Panel for a vote:

Question 1

Is there reasonable assurance that the CHAMPION[™] HF Monitoring System is safe for use in patients who meet the criteria specified in the proposed indications?

The panel voted **9-1 in favor.**

Question 2

Is there reasonable assurance that the CHAMPION[™] HF Monitoring System is effective for use in for patients who meet the criteria specified in the proposed indications?

The panel voted **7-3 against.**

Question 3

Do the benefits of the CHAMPION™ HF Monitoring System for use in patients who meet the criteria specified in the proposed indications outweigh the risks for use in patients who meet the criteria specified in the proposed indications?

The panel voted **6-4 against.**

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