

***Voting Questions
for the
Circulatory System Devices Advisory Panel***

December 8, 2011

The CHAMPION™ HF Monitoring System

The CHAMPION™ HF Monitoring System is a permanently implantable pressure measurement system designed to provide daily pulmonary arterial pressure measurements including systolic, diastolic and mean PA pressure. These measurements are used to guide treatment of congestive heart failure. The system consists of the following:

- **Implantable Sensor** - The Pressure Sensor is 15mm in length, 3.41mm in width and is 2mm thick, consisting of a three dimensional coil and pressure sensitive capacitor encased between two wafers of fused silica. The coil (inductor) electro-magnetically couples to the Sensor and allows the remote measurement of the resonant frequency of the LC circuit. This allows for wireless communication with the Sensor and eliminates the need for an on-board source of energy, such as a battery.
- **Delivery System** – The Delivery System allows the placement of the Pressure Sensor within the distal pulmonary artery. There are two versions of the Delivery System. The first includes a hydrophilic coating on the distal portion of the catheter shaft and the second has no coating on the catheter shaft. Both delivery catheters have a usable length of 120cm and are compatible with a 0.018" guidewire. The Delivery System (with HF Sensor) is introduced over a guidewire through an 11Fr sheath. Tether wires connect the Sensor to the Delivery System until the physician determines that the Sensor is properly positioned within the distal pulmonary artery. Once the Sensor is in position, the tether wires are withdrawn, releasing the Sensor.
- **Electronics Unit (Interrogator) and database** - The Electronics Unit contains hardware and software to acquire and process signals from the sensor, provides a user-friendly system interface for both patients and clinicians, and transfers PA measurements to a secure database for review by medical professionals. The database is a web based server that contains software, which receives data transmitted from the electronics unit, and presents the data for review by medical professionals.

CHAMPION™ HF Monitoring System Panel Meeting

The sponsor has proposed the following Indications for Use:

The CHAMPION™ HF Monitoring System is indicated for measuring pulmonary artery pressures in patients with New York Heart Association (NYHA) Class III heart failure.

The following questions relate to the approvability of the CHAMPION™ HF Monitoring System. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented at the panel meeting.

Voting 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 indication?

Voting 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 indication?

Voting Question 3:

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