

# Voting Questions

## Circulatory System Devices Panel of the Medical Devices Advisory Committee

March 16, 2016

Premarket Application: (P150009) Angel Medical Systems Incorporated

### AngelMed Guardian System

The sponsor has proposed the following Indications for Use:

*The AngelMed Guardian is an implantable cardiac monitor indicated for use to alert patients at risk for acute coronary syndrome to ST segment shifts indicating coronary ischemia. The device is indicated to reduce the probability of death, a new Q wave MI, and late arrival at a medical facility (>2 hours following ST shift detection) for patients having a confirmed thrombotic closure of a coronary artery with or without associated symptoms.*

**The following questions relate to the approvability of the AngelMed Guardian System. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.**

**Voting Question 1:**

**Is there reasonable assurance that the AngelMed Guardian System is safe for patients who meet the criteria specified in the proposed indication?**

**Voting Question 2:**

**Is there reasonable assurance that the AngelMed Guardian System is effective for use in patients who meet the criteria specified in the proposed indication?**

**Voting Question 3:**

**Do the benefits of the AngelMed Guardian System outweigh the risks for use in patients who meet the criteria specified in the proposed indication?**

Panel members will be asked to state how they answered each question and to explain their answers.