

**Premarket Approval (PMA) Package for  
Dockets Management Branch**

**PMA Number P030011  
Docket # 2004M-0471**

**Syncardia Systems, Inc.  
Syncardia Temporary CardioWest Total  
Artificial Heart (TAH-t)**

**Includes:**

**Approval Order  
Summary of Safety and Effectiveness Data (SSED)  
Labeling**

*2004M-0471*

*AAV 1*