

**AGENDA**  
**CIRCULATORY SYSTEM DEVICES PANEL**

June 8, 2004

Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Parkway, Gaithersburg, MD.

<b>8:00 – 5:00</b>	<b>PMA Discussion, Recommendations, and Voting</b>
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<b>8:00 a.m.</b>	<b>Call to Order</b>	<b>Warren Laskey, M.D.</b> <b>Chairperson</b>
<b>8:05 – 8:30 a.m.</b>	<b>*Open Public Session*</b>	
<b>8:30 – 9:30 a.m.</b>	<b>Sponsor Presentation: World Heart P0980012/S004: Novacor N100PC and N100PC(q) Left Ventricular Assist System (LVAS)</b>	
<b>9:30 – 9:45 a.m.</b>	<b>Questions and Answers</b>	
<b>9:45 – 10:00 a.m.</b>	<b>Break</b>	
<b>10:00 – 11:00 a.m.</b>	<b>FDA Presentation</b>	
<b>11:00 – 11:15 a.m.</b>	<b>Questions and Answers</b>	
<b>11:15 – 12:00 p.m.</b>	<b>Open Committee Discussion</b>	<b>Warren Laskey, M.D.</b>
<b>12:00 p.m.</b>	<b>Adjourn – Break for Lunch</b>	
<b>1:00 – 1:15 p.m.</b>	<b>Call to Order</b>	
<b>1:15 – 3:45 p.m.</b>	<b>Open Committee Discussion</b>	<b>Warren Laskey, M.D.</b>
<b>3:45 – 4:00 p.m.</b>	<b>Break</b>	
<b>4:00 – 5:00 p.m.</b>	<b>*Open Public Session*</b> <b>FDA Comments</b> <b>Sponsor Comments</b> <b>Recommendations &amp; Vote</b>	<b>Warren Laskey, M.D.</b>
<b>5:00 p.m.</b>	<b>Adjourn</b>	

**OPEN PUBLIC HEARINGS\***

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Wood will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question

**them further. Dr. Laskey will recognize unscheduled speakers as time allows.**

**Note: Only the Chair and members of the Panel may question speakers during the open public hearing.**