

**DRAFT**

**NEUROLOGICAL DEVICES PANEL  
of the  
MEDICAL DEVICES ADVISORY COMMITTEE**

*Nineteenth Meeting*  
**Hilton Washington, D.C. North  
620 Perry Parkway  
Gaithersburg, Maryland  
June 17, 2005**

**Panel Chairperson**  
**Secretary**  
Stephen J. Haines, M.D.

**Executive**  
Janet L. Scudiero, M.S.

**8:30 am Call to Order**  
**Conflict of Interest and Deputization to Voting Member Status Statements**  
**Panel Introductions**  
**Critical Path Initiative**, Sousan S. Altaie, Ph.D.  
**Postmarket Study Design**, Susan N. Gardner, Ph.D.  
**Division Update**, Theodore R. Stevens, M.S.

**Olympic Medical Corporation, Olympic Cool-Cap®, PMA P040025**

**9:15 am 1<sup>st</sup> Open Public Hearing\***

**9:45 am Sponsor Presentation**  
Edward B. Weiler, Ph.D., Vice President, Research & Development.  
Seattle, WA  
John S. Wyatt, M.D., University College Hospital, London, England  
Ping-Yu Liu, Ph.D., Drug & Device Development Co., Inc., Redmond, WA

**10:45 am Break**

**11:00 am FDA Presentation**  
Kristen A. Bowsher, Ph.D.  
Susan K. McCune, M.D.  
Jianxiong Chu, Ph.D.

**12:00 m Lunch**

**1:00 pm Deliberations**  
Reese M. Clark, MD

**3:30 pm Break**

**3:45 pm FDA and Sponsor Summations**, up to 15 minutes each

**4:15 pm Panel Vote**

**5:00 pm Adjournment**

\* **Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.