

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

Twentieth Meeting  
Hilton Washington DC North  
620 Perry Parkway  
Gaithersburg, Maryland  
January 26, 2007

Panel Chairperson  
Thomas G. Brott, M.D.

Executive Secretary  
Janet L. Scudiero, M.S.

8:00 am Call to Order  
Conflict of Interest Statement  
Panel Introductions  
Update since June 17, 2005, Peter D. Rumm, M.D., M.P.H., Deputy Director, DGRND, and  
Joshua C. Nipper, Acting Chief, REDB, DGRND

*Neuronetics, Inc., NeuroStar TMS System, K061053*

8:15 am Open Public Hearing\*  
8:45 am Sponsor Presentation

Judy P. Ways, Ph.D., Vice President, Regulatory Affairs and Quality Assurance  
Mark A. Demitrack, M.D, Vice President and Chief Medical Officer  
Alan F. Schatzberg, M.D., M.D., Professor and Chairman, Psychiatry, Stanford University,  
Consultant  
Michael E. Thase, M.D., Professor, Psychiatry, University of Pennsylvania, Consultant  
Judy P. Ways, Ph.D.

9:45 am Break

10:00 am FDA Presentation

Kristen A. Bowsher, Ph.D., Biomedical Engineer, 510(k) Team Leader, DGRND  
Victor Krauthamer, Ph.D., Neurophysiologist, DP, OSEL  
Ann H. Costello, Ph.D., D.M.D., Medical Officer, DGRND  
Pablo E. Bonangelino, Ph.D., Biostatistician, DBS, OSB  
Ann H. Costello, Ph.D., D.M.D.

11:00 am Panel Deliberations

12:00 pm Lunch

1:00 pm Panel Deliberations

2:45 pm Open Public Hearing\*

3:15 pm Break

3:30 pm FDA and Sponsor Summations

4:00 pm Panel Deliberations: FDA Questions

4:50 pm Break

## *Conditions of Approval Study Reports*

- 5:05 pm Conditions of Approval Study Reports Overview**  
**Susan N. Gardner, Ph.D., Director, OSB**
- 5:15 pm Open Public Hearing**
- 5:30 pm Confluent Surgical, Inc., DuraSeal Dura Sealant System, P040034, April 7, 2005**  
**Eric P. Ankerud, J.D., Vice President, Clinical, Regulatory, and Quality, Confluent Surgical, Inc.**  
**Kahn W. Li, M.D., Medical Officer, DGRND, ODE**  
**Panel Discussion**
- 6:00 pm Cyberonics, Inc., Implanted Vagus Nerve Stimulation System, P970003/S50, July 15, 2005**  
**Richard L. Rudolph, M.D., Vice President of Clinical and Medical Affairs and Chief Medical Officer, Cyberonics, Inc.**  
**Danica Marinac-Dabic, M.D., Ph.D., Medical Officer, Chief, EB, DPS, OSB**  
**Panel Discussion**
- 6:30 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.