

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

*Twelfth Meeting*

**9200 Corporate Boulevard**  
**Rockville, Maryland**  
**September 16 and 17, 1999**

**Panel Chairperson**  
Alexa I. Canady, M.D.

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

**September 17, 1999**

- 8:30 am Call to Order**  
**Conflict of Interest and Deputization to Voting Member Status Statements**  
**Panel Introductions**
- 8:45 am Postmarket Surveillance Update**
- 9:15 am Draft "Guidance Document for Neurological Embolization Devices"**
- Open Public Hearing, 30 minutes**  
**FDA Presentation**  
**Industry Presentation**  
**Panel Discussion**  
**Panel Recommendations**
- 11:30 am Lunch**
- 12:30 pm Reclassification Petition for the Totally Implanted Spinal Cord Stimulator for Pain Relief**
- Open Public Hearing, 30 minutes**  
**FDA Presentation**  
**Petitioner Presentation**  
**Industry Presentation**
- 2:00 pm Break**
- FDA Questions**  
**Panel Discussion**  
**Open Public Hearing, near the end of the panel's deliberations, 30 minutes**  
**Concluding Discussion, Completion of the Classification**  
**Questionnaire and Supplemental Data Sheet and Vote**
- 3:30 pm Adjournment**