MEETING AGENDA

ORTHOPEDIC AND REHABILITATION DEVICES PANEL of the MEDICAL DEVICES ADVISORY COMMITTEE Hilton Washington DC North 620 Perry Parkway Gaithersburg, Maryland

September 19, 2006

Panel Chairperson (Acting) Jay D. Mabrey, M.D. **Executive Secretary** Ronald P. Jean, Ph.D.

8:30 a.m. Call to Order Conflict of Interest and Deputization to Voting Member Status Statements Panel Introductions Update since the June 2, 2006 Meeting

Medtronic Sofamor Danek, Prestige Cervical Disc System, P060018

1st Open Public Hearing* 9:15 a.m. 9:45 **Sponsor Presentation** a.m. 10:45 Break a.m. 11:00 a.m. **FDA** Presentation 11:45 **Panel Deliberations** a.m. 12:30 p.m. Lunch 1:30 **Panel Deliberations and FDA Questions** p.m. 2nd Open Public Hearing* 3:30 p.m. 4:00 Break p.m. 4:15 **FDA and Sponsor Summations** p.m. 4:45 **Panel Vote** p.m. 5:30 p.m. 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.