

Seventieth Meeting of the
Obstetrics and Gynecology Devices Panel

Thursday, June 23, 2005
Holiday Inn, Gaithersburg, MD

Neoventa STAN[®] S31 Fetal Heart Monitoring System (P020001)
Draft Agenda*

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| 9:00-9:05 | Call to order |
| 9:05-9:20 | “Critical Path Initiative at the FDA” presentation <ul style="list-style-type: none">• Sousan S. Altaie, PhD, Scientific Policy Advisor, Office of In Vitro Diagnostic Device Evaluation and Safety |
| 9:20-9:30 | Introductory remarks <ul style="list-style-type: none">• Colin Pollard, Chief, Obstetrics and Gynecology Devices Branch |
| 9:30-10:00 | Open public hearing** |
| 10:00-11:00 | Sponsor presentation <ul style="list-style-type: none">• Marie Marlow, President and CEO, M Squared Associates• Lawrence D. Devoe, MD, Chairperson, Department of Obstetrics and Gynecology, Medical College of Georgia, Augusta, GA• Simon Grant, CEO, Neoventa Medical AB• Sue Ellen Abney, RNC, MSN, Perinatal Clinical Nurse Specialist Medical College of Georgia, Augusta, GA• Jennifer L. Ryea, ScM, Biostatistician, Hogan & Hartson L.L.P. |
| 11:00-11:15 | Break |
| 11:15-12:15 | FDA presentation <ul style="list-style-type: none">• Kathryn S. Daws-Kopp• Julia Carey-Corrado, M.D.• Gene Pennello, Ph.D. |
| 12:15-1:00 | Lunch |
| 1:00-3:15 | Panel discussion |
| 3:15-3:30 | Break |
| 3:30-4:00 | Open public hearing** |
| 4:00-5:00 | Panel deliberations and vote |
| 5:00 | Adjourn |

** all times are approximate*

**** Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the meeting agenda. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, Dr. Noller will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.