

**Sixty-Fourth Meeting of the  
Obstetrics and Gynecology Devices Panel**

*Gaithersburg Holiday Inn, Gaithersburg, Maryland*

**Agenda, Monday, May 21, 2001\***

*Mallinckrodt OxiFirst® Fetal Oxygen Saturation Monitoring System, Model N-400  
(P990053/S1)*

- 1:00-1:30     Introductory remarks
- *Colin Pollard, Chief, Obstetrics & Gynecology Devices Branch*
- 1:30-2:00     Open public hearing
- *ACOG, George Macones, M.D., University of Pennsylvania*
- 2:00-2:30     Presentation by NIH
- *Cathy Spong, M.D., Chief, Pregnancy and Perinatology Branch, PPB CRMC NICHD NIH*
- 2:30-3:00     Presentation by Mallinckrodt
- *Simon Thomas - Former Director of Perinatal Marketing and Former Senior Director of Perinatal Research & Development, Nellcor Business Unit of Tyco Healthcare's Respiratory Division*
  - *Richard P. Porreco, MD - Principal Investigator, Dystocia Study, Presbyterian/St. Luke's Medical Center, Denver, CO*
- 3:00-3:45     Panel discussion
- 3:45-4:00     Panel vote

*Novatrix Labor Assister Device: Discussion of Regulatory Process Issues*

- 4:00-4:05     Introductory remarks
- *Colin Pollard, Chief, Obstetrics & Gynecology Devices Branch*
- 4:05-4:30     Presentation by CareStat
- *Howard Golub, Ph.D., M.D., President*
- 4:30-5:00     Questions from panel
- 5:00            Adjourn

*\*all times are approximate*