

## **Obstetrics and Gynecology Devices Panel**

Monday, May 21, 2001 – 1-4 p.m.

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

#### Panel Discussion Questions

When the FDA approved the PMA for the OxiFirst® monitor (May 12, 2000), a post-approval study was required to assess how the use of this monitor would impact cesarean deliveries, as well as to evaluate several other important variables within general clinical practice. Per FDA's approval order, the post-approval study should address the following parameters.

- indication(s) for OxiFirst® sensor placement
- Cesarean-section rates
- maternal infection rates
- duration that fetal oxygen saturation can remain below 30% before risk of fetal injury
- adequacy of labor
- neonatal outcomes (e.g., cord blood gases, Apgar scores, etc.)

In the PMA Supplement subject to this panel discussion, Mallinckrodt has proposed a post-approval study plan based on the three separate studies:

Study A – 3-arm multi-center randomized trial conducted by NICHD's MFMU Network, with some technical consultation from Mallinckrodt

Study B – 'General Use Study' sponsored by Mallinckrodt

Study C – 'Dystocia Study' conducted by some of the original OxiFirst® investigators and partially underwritten by Mallinckrodt

#### Study A

1. In the NIH study, the OxiFirst sensor will be placed in subjects for indications beyond what is in the approved labeling (i.e., non-reassuring FHR tracing). Will the proposed NIH study provide useful data, per the panel's earlier recommendation, on the currently approved indication? If not, are there patient subsets that can be analyzed?
2. The FSpO<sub>2</sub> "cut-off" specified in the OxiFirst® labeling is 30%. Will the sham arm of the NIH study provide information towards further understanding of the validity of this cut-off value?
3. Will the labor management protocol employed in the NIH study allow for meaningful interpretation with respect to the management protocol in the approved labeling?

### Study B – General Use Study

4. Considering the nature of the clinical centers involved in the NIH study and Dystocia Study, should the “General Use Study” target different types of hospital settings so as to optimize the overall information gained by the sum of the three studies?
5. What would be the appropriate overall timeframe for the conduct of this study? Is there a need for longer term tracking?
6. Are there any other improvements that can be made to the clinical protocol?

### Study C – Dystocia Study

7. Will this study help elucidate the findings from the pivotal PMA study that showed more cesarean deliveries for dystocia in the OxiFirst® arm?

### Background Materials

- FDA Approval Package for the PMA: <http://www.fda.gov/cdrh/pdf/p990053.html>
- Garite, T.J., Dildy, G.A., McNamara, H., Nageotte, M.P., Boehm, F.H., Dellinger, E.H., Knuppel, R.A., Porreco, R.P., Miller, H.S., Sunderji, S., Varner, M.W., Swedlow, D.B., “A multicenter controlled trial of fetal pulse oximetry in the intrapartum management of nonreassuring fetal heart rate patterns,” *Am J Ob Gyn* 183:1049-1058, 2000.\*
- Summary of post-approval clinical study plans (attachment 1)

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