OxiFirst Fetal Oxygen Saturation Monitoring System

This is a brief overview of information related to FDA's approval to market this product. See Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	OxiFirst™ Fetal Oxygen Saturation Monitoring System
Manufacturer:	Mallinckrodt Nellcor Perinatal Business
Address:	4380 Hacienda Drive, Pleasanton, CA 94588
Approval Date:	May 12, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990053a.pdf

What is it? A new type of fetal monitor that measures oxygen saturation in the baby's blood as a sign of fetal health during labor and delivery.

How does it work? The OxiFirst™ sensor is inserted into the mother's uterus and placed against the temple or cheek of the fetus. The monitor displays fetal oxygen saturation as the percentage of oxygen in the fetus's blood.

When is it used? Oxifirst™ should be used along with conventional electronic fetal monitoring when the fetal heart rate is "non-reassuring," that is, when it indicates that the baby may be in distress due to lack of adequate oxygen. It is intended for use only on single (not multiple) fetuses of at least 36 weeks gestation, where the mother's water has broken and the fetal head is in the normal, head down, position for delivery.

What will it accomplish? Fetal heart rate (FHR) patterns are an indirect measure of how much oxygen is in the fetus' blood. For the past 30 years, clinicians have used FHR evaluation as the primary way to evaluate fetal status during labor. It is hoped that the understanding of fetal condition during labor will improve as a result of the additional information that comes from measuring fetal oxygen levels with this new monitor.

In the pivotal clinical study that supported approval, the overall rate of Cesarean sections (c-sections) was unchanged whether or not the new monitor was used. However, use of the monitor did reduce c-sections for a subgroup of patients diagnosed with a non-reassuring fetal status. This indicates that clinical understanding of fetal condition during labor improved with the use of this new monitor. FDA has required the sponsor to conduct a post approval study to see how c-section rates are affected as the monitor is introduced into general clinical practice.

When should it not be used? This device should not be used in the presence of flammable anesthetics, or to monitor patients during water births, in whirlpool or submersion water baths, during showers, or any other situation where the mother is immersed in water. The device should not be used in women with active genital herpes, HIV, or Hepatitis B and/or Hepatitis E antigens.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p990053.html
Other: http://jama.ama-assn.org/issues/v284n1/ffull/jfd00005-2.html