

## **BACKGROUND**

The Anesthesiology and Respiratory Devices Branch (ARDB), Office of Device Evaluation, reviews over twenty 510(k) submissions annually for pulse oximeters. The ARDB has received submissions for reflectance pulse oximetry sensors intended for use in neonates and for pulse oximeters intended to be marketed over-the-counter (OTC) as medical devices. The current pulse oximeter guidance document, available at <http://www.fda.gov/cdrh/ode/guidance/997.pdf>, does not provide recommendations on either of these topics and needs to be updated. The branch would like the panel to offer recommendations to FDA on reflectance pulse oximetry in neonates and OTC use of pulse oximeters.

## **PANEL ACTION**

At this meeting, the Anesthesiology and Respiratory Therapy Devices Panel will discuss and make recommendations regarding general pulse oximeter issues.