FDA 501(k) Clearance for Pulse Oximetry Equipment Use in Neonates
Instructions for Use of FDA Website
August 21, 2012

1. Go to the following link on the FDA website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

2. Enter known information for the pulse oximeters device and/or sensor.
   Hint: The applicant is the oximeter company. Supply the information that you know; you do not need to fill in all fields.
3. If a list of devices appears, click on the appropriate device for more information.

4. Additional information about the device will appear. Select “Summary”.
5. Review the Summary, the “Intended USE/Indications for Use” Section will state whether device is cleared for Neonatal Use.