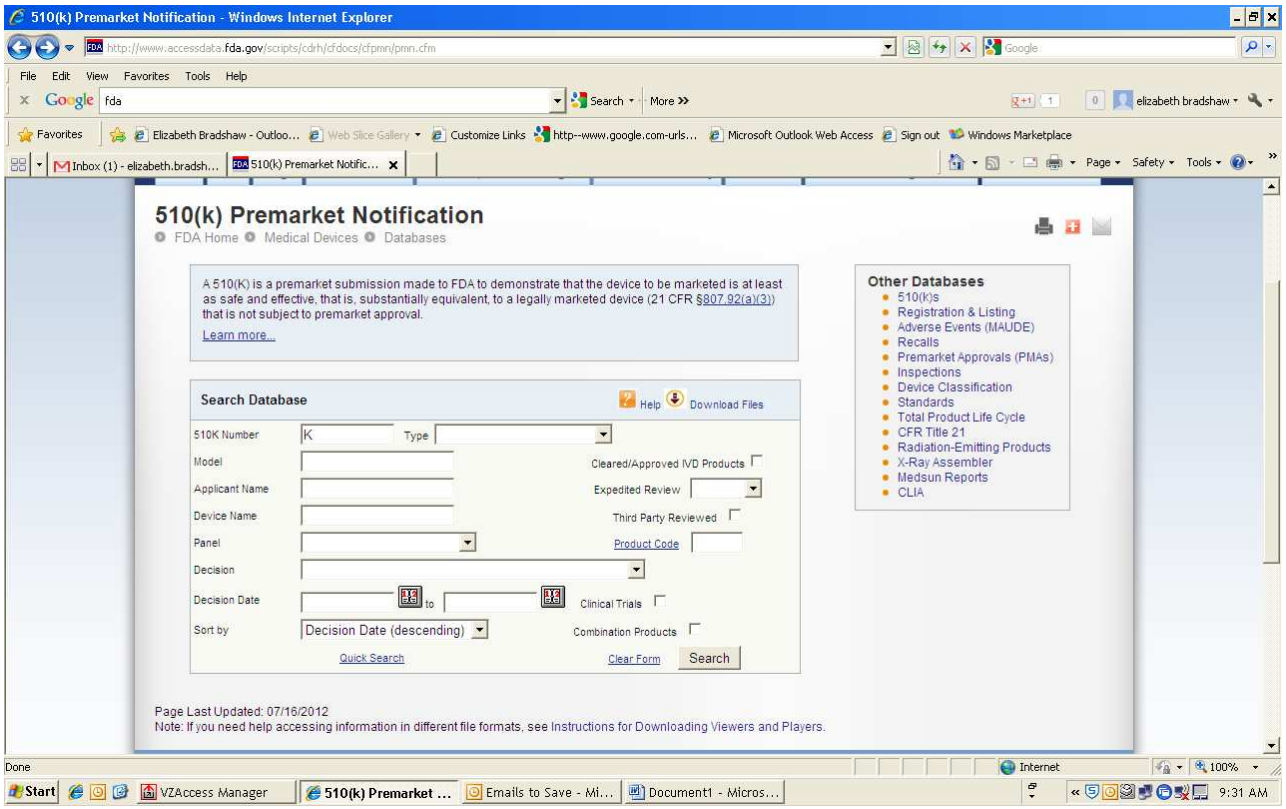
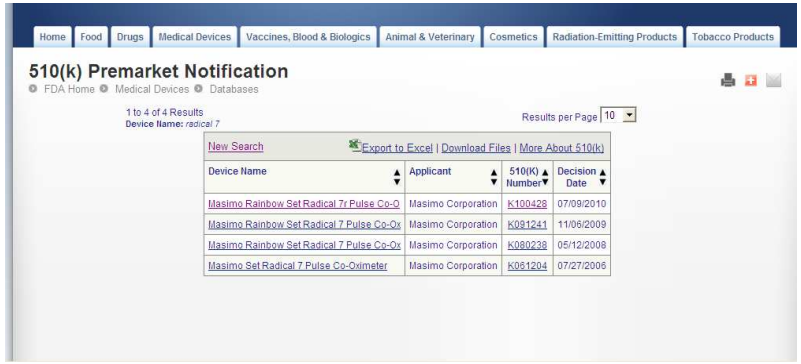
FDA 501(k) Clearance for Pulse Oximetry Equipment Use in Neonates
Instructions for Use of FDA Website
August 21, 2012

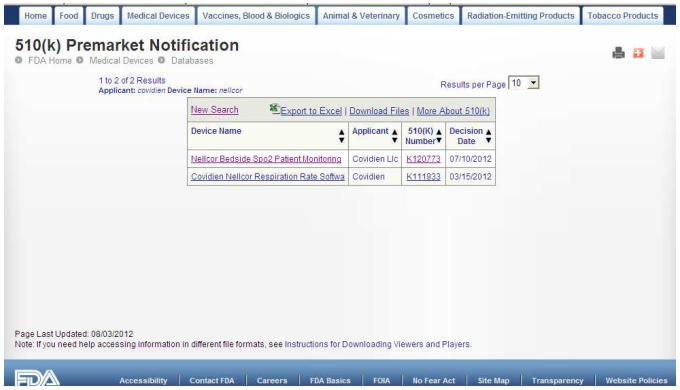
1. Go to the following link on the FDA website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

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.

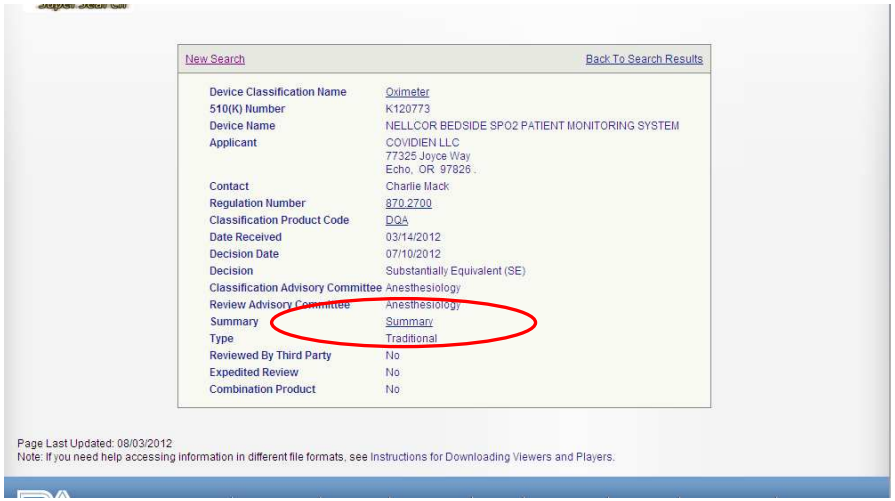


3. If a list of devices appears, click on the appropriate device for more information.

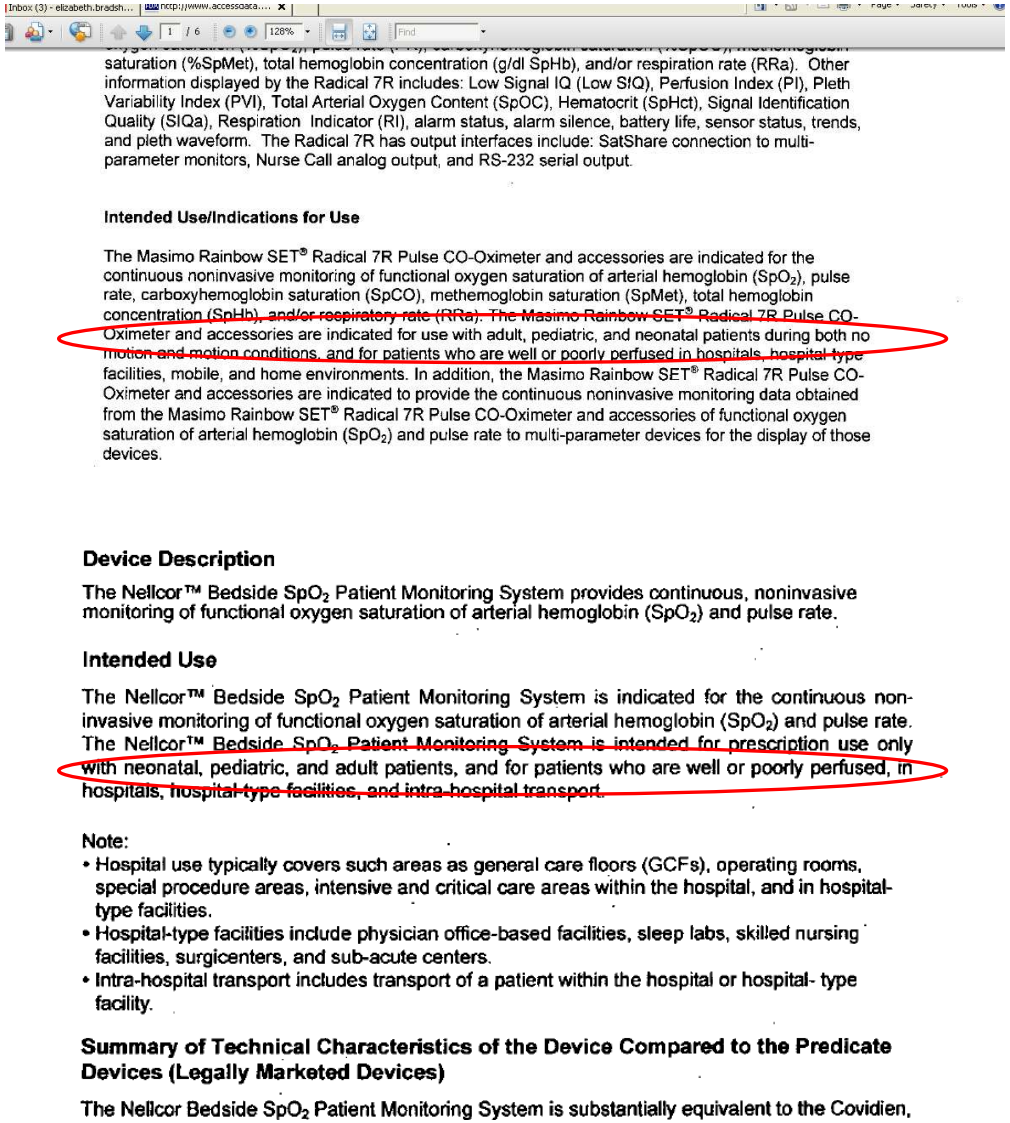




4. Additional information about the device will appear. Select “Summary”.



5. Review the Summary, the "Intended USE/Indications for Use" Section will state whether device is cleared for Neonatal Use.



saturation (%SpMet), total hemoglobin concentration (g/dl SpHb), and/or respiration rate (RRa). Other information displayed by the Radical 7R includes: Low Signal IQ (Low SIQ), Perfusion Index (PI), Pleth Variability Index (PVI), Total Arterial Oxygen Content (SpOC), Hematocrit (SpHct), Signal Identification Quality (SIQa), Respiration Indicator (RI), alarm status, alarm silence, battery life, sensor status, trends, and pleth waveform. The Radical 7R has output interfaces include: SatShare connection to multi-parameter monitors, Nurse Call analog output, and RS-232 serial output.

Intended Use/Indications for Use

The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated to provide the continuous noninvasive monitoring data obtained from the Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

Device Description

The Nellcor™ Bedside SpO_2 Patient Monitoring System provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

Intended Use

The Nellcor™ Bedside SpO_2 Patient Monitoring System is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Nellcor™ Bedside SpO_2 Patient Monitoring System is intended for prescription use only with neonatal, pediatric, and adult patients, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, and intra-hospital transport.

Note:
- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.
- Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.
- Intra-hospital transport includes transport of a patient within the hospital or hospital- type facility.

Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The Nellcor Bedside SpO_2 Patient Monitoring System is substantially equivalent to the Covidien,