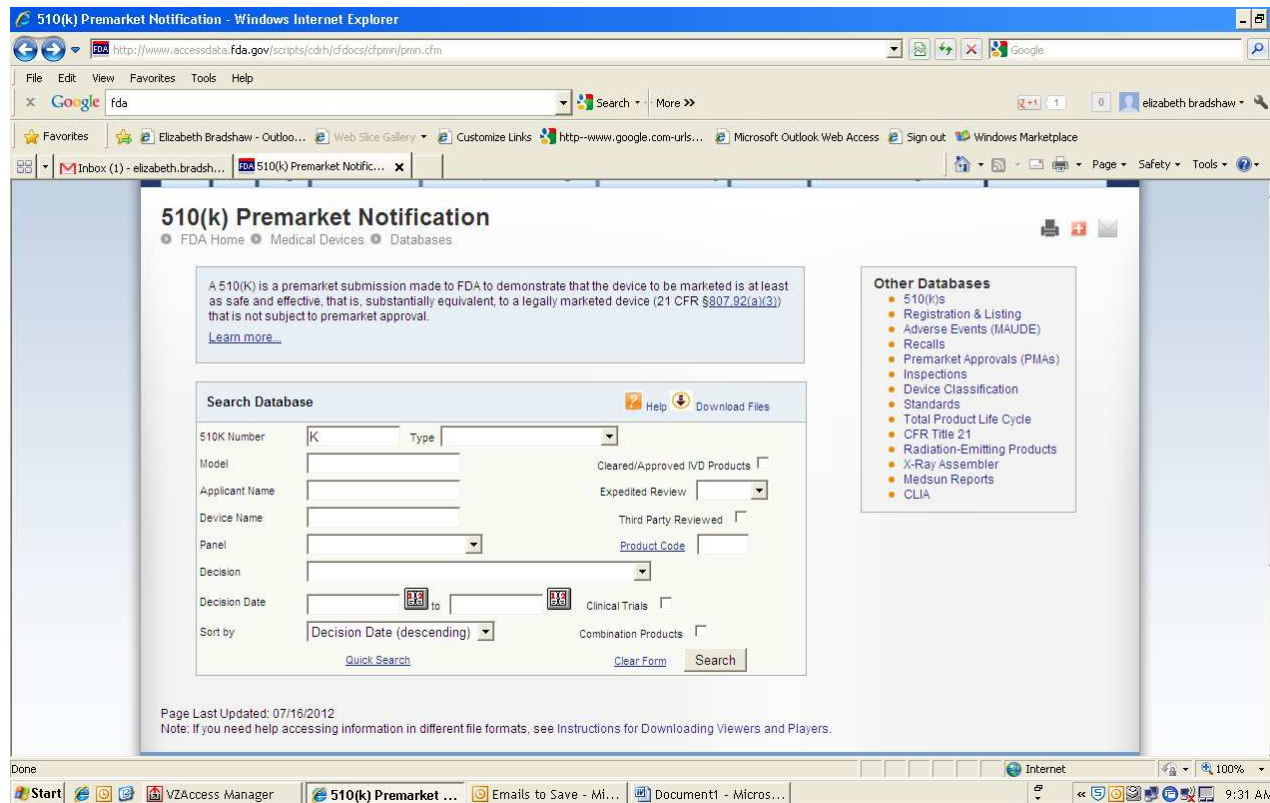


FDA 501(k) Clearance for Pulse Oximetry Equipment Use in Neonates

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.

510(k) Premarket Notification

1 to 4 of 4 Results
Device Name: radical 7

Device Name	Applicant	510(k) Number	Decision Date
Masimo Rainbow Set Radical 7 Pulse Co-O	Masimo Corporation	K100428	07/09/2010
Masimo Rainbow Set Radical 7 Pulse Co-Ox	Masimo Corporation	K081241	11/06/2009
Masimo Rainbow Set Radical 7 Pulse Co-Ox	Masimo Corporation	K080238	05/12/2008
Masimo Set Radical 7 Pulse Co-Oximeter	Masimo Corporation	K081204	07/27/2006

510(k) Premarket Notification

1 to 2 of 2 Results
Applicant: covidien Device Name: nellcor

Device Name	Applicant	510(k) Number	Decision Date
Nellcor Bedside SpO2 Patient Monitoring	Covidien LLC	K120773	07/10/2012
Covidien Nellcor Respiration Rate Software	Covidien	K111023	03/15/2012

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

New Search [Back To Search Results](#)

Device Classification Name: [Oximeter](#)

510(K) Number: K111403

Model: PRONTO-7

Device Name: MASIMO RAINBOW SET PRONTO-7 PULSE CO-OXIMETER AND ACCESSORIES

Applicant: MASIMO CORPORATION
40 Parker
Irvine, CA 92618

Contact: Anil Bhalani

Regulation Number: [870.2700](#)

Classification Product Code: [DQ4](#)

Subsequent Product Code: [GLY](#)

Date Received: 05/19/2011

Decision Date: 12/30/2011

Decision: Substantially Equivalent (SE)

Classification Advisory Committee: Anesthesiology

Review Advisory Committee: Anesthesiology

Summary: [Summary](#)

Type: Traditional

Reviewed By Third Party: No

Expedited Review: No

Combination Product: No

New Search [Back To Search Results](#)

Device Classification Name: [Oximeter](#)

510(K) Number: K120773

Device Name: NELLCOR BEDSIDE SPO2 PATIENT MONITORING SYSTEM

Applicant: COVIDIEN LLC
77325 Joyce Way
Echo, OR 97826

Contact: Charlie Mack

Regulation Number: [870.2700](#)

Classification Product Code: [DQ4](#)

Date Received: 03/14/2012

Decision Date: 07/10/2012

Decision: Substantially Equivalent (SE)

Classification Advisory Committee: Anesthesiology

Review Advisory Committee: Anesthesiology

Summary: [Summary](#)

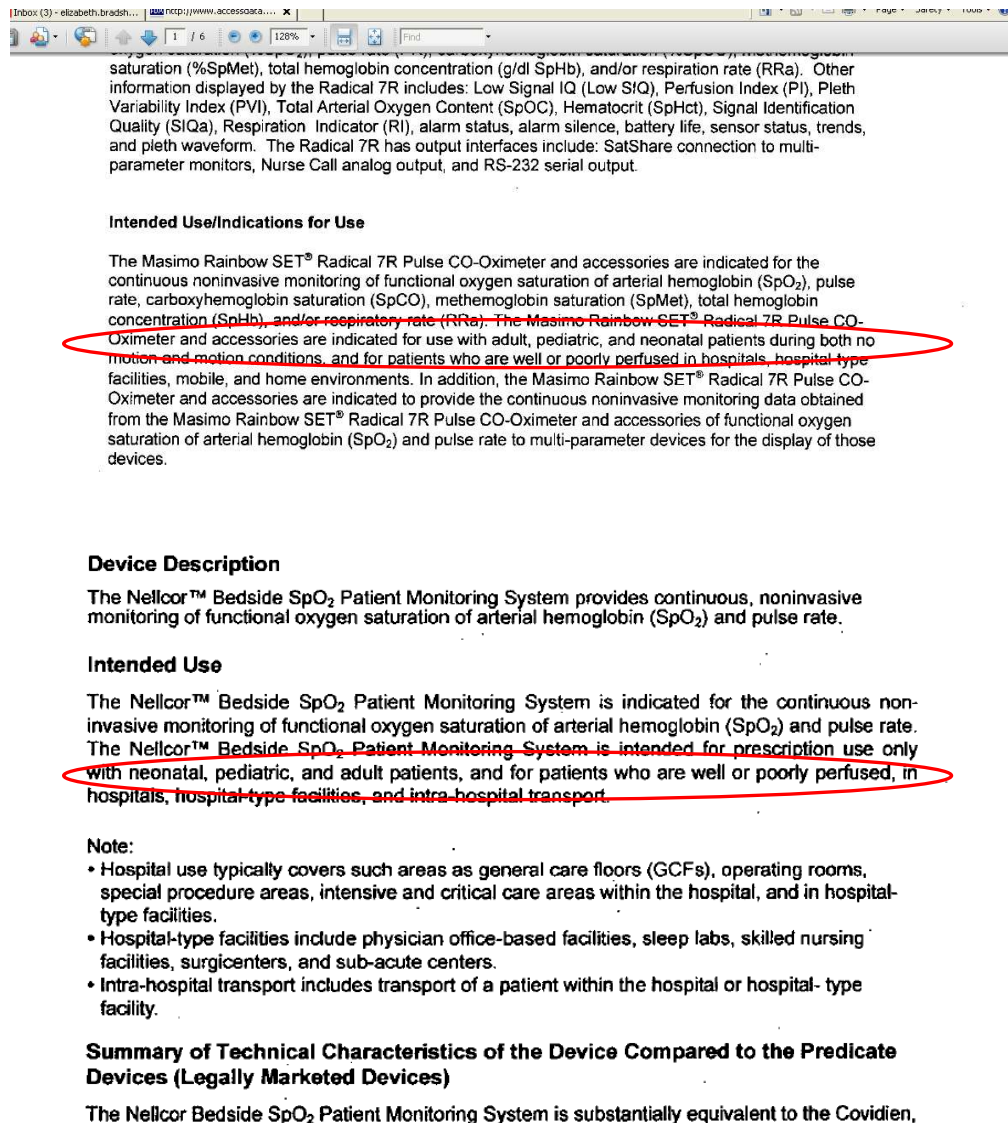
Type: Traditional

Reviewed By Third Party: No

Expedited Review: No

Combination Product: No

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 (SpO₂), 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 (SpO₂) and pulse rate to multi-parameter devices for the display of those devices.

Device Description

The Nellcor™ Bedside SpO₂ Patient Monitoring System provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate.

Intended Use

The Nellcor™ Bedside SpO₂ Patient Monitoring System is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The Nellcor™ Bedside SpO₂ 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 SpO₂ Patient Monitoring System is substantially equivalent to the Covidien,