

3.4 Classification

3.4.1 Class

Pulse Oximeter Finger Probes/Sensors are an accessory to the Pulse Oximeter as published by the FDA in the Final rule in the February 5 Federal Register 45, 7905, 1980, classifying the Pulse Oximeter as a Class II medical device (performance standards).

3.4.2 Panel

Oximeter finger belongs to the General panel.

3.4.3 Product Code

80VFN

3.5 Performance Standards

Performance standards have not been promulgated for Pulse Oximeter Finger Probes/Sensors.

3.6 Labeling

3.6.1 Product Description

The Medical Cables SpO₂ Finger Probe is recommended for short term SpO₂ monitoring on pediatric and adult patients. Pulse oximetry measures both arterial oxygen saturation (SpO₂) and pulse rate without skin penetration, electrical contact, or heat transfer. Medical Cables, Inc., SpO₂ Finger Probes are a reusable clip-on sensor with the optical components protected in a hard plastic casing. The probes consist of three optical components, two light sources and a detector. The light sources are two light emitting diodes (LED), one Red (640-680 nm) and one Infrared (940-980 nm). The detector is a photodiode, which is an electrical device that produces a current proportional to the incident light intensity. Medical Cables SpO₂ Finger Probe connects between the patient and a Pulse Oximeter currently marketed under FDA listings according to the Table 3.2.

3.6.2 Photograph

See Appendix 1 for Photographs of Medical Cables, Inc. SpO₂ Finger Probes

3.6.3 Labels

See Appendix 2 for Medical Cables, Inc. SpO₂ Finger Probe labels

3.6.4 Instructions for Use

See Appendix 3 for Medical Cables, Inc. SpO₂ Finger Probe User Instructions