

Classification Rationale

Product Family	2160 SpO2		
Type	Rule	Class	Additional Information
Non-Invasive	Rule 1	1Ib	
Active	Rule 1 & 11		Monitors – SpO2
Invasive	No		
Special	No		

Flow chart includes: Yes or No

Classified by: ...J.S.Lamb.....

Date: 01/10/2009

The Device uses skin contact and is non-invasive.

It does not administer or exchange energy, fluids ,solids or gases. .

The 2101 is intended for use as a spot monitor for periods of not more than 60 Minutes

However it can be used for longer periods as it has 48hr trends.

The 2101 can be used in critical care areas