

**K182868 INVOS PM7100 Patient Monitor, INVOS Adult rSO2  
Sensor**Jan 8, 2019  
88 days to decisionK182868 · Product code: **MUD** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k182868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Oct 12, 2018
Decision date	Jan 8, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	Samir Ibrahim
510(k) history	89 submissions · 86 cleared · 2010-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182868/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026