

K211561 INVOS PM7100 Patient Monitor, INVOS Pediatric rSO2 Sensor, INVOS Infant Regional Saturation Sensor (also referred to as OxyAlert NIRSensor)Dec 5, 2021
199 days to decisionK211561 · Product code: **MUD** · Neurology
Source: <https://www.510kdatabase.net/k211561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	May 20, 2021
Decision date	Dec 5, 2021
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Megan Elliott
510(k) history	88 submissions · 85 cleared · 2010-2026

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