

**K212555 Nellcor OxySoft Neonatal-Adult SpO2 Sensor,  
OxySoftN, Nellcor OxySoft Neonatal-Adult SpO2 Sensor,  
OxySoftNHC**May 6, 2022  
266 days to decisionK212555 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k212555/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 13, 2021
Decision date	May 6, 2022
Days to decision	266 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	Anushka Jayaraman
510(k) history	88 submissions · 85 cleared · 2010-2026

**CLINICAL EVIDENCE - NCT04559763**

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**SpO2 Accuracy Validation of the OxySoft Sensor Via Reference CO-Oximetry Motion Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	16 patients (actual)
Study sites	1 site
Condition studied	Hypoxia; Desaturation of Blood
Study type	Observational
Completion date	Aug 21, 2020
Sponsor	Medtronic - MITG (Industry)

**Primary outcome**

To investigate performance of the OxySoft device by measuring oxygen saturation accuracy during motion and non-motion conditions

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04559763](https://clinicaltrials.gov/study/NCT04559763)

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