

**K221282 Empatica Health Monitoring Platform**Nov 20, 2022  
201 days to decisionK221282 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k221282/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 3, 2022
Decision date	Nov 20, 2022
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Empatica S.R.L.</b>
Location	Milano, IT
Contact	Alberto Poli
510(k) history	8 submissions · 8 cleared · 2018-2025

**CLINICAL EVIDENCE - NCT04964609****EmbracePlus SpO2 Accuracy Validation**

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Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	14 patients (actual)
Study sites	1 site
Condition studied	Oximetry
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 21, 2022
Sponsor	Empatica, Inc. (Industry)

**Primary outcome****SpO2 Accuracy**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04964609](https://clinicaltrials.gov/study/NCT04964609)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).  
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