

K241090 Evie Med RingNov 29, 2024
221 days to decisionK241090 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k241090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Apr 22, 2024
Decision date	Nov 29, 2024
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Movano Inc. Db a Movano Health
Location	Pleasanton, CA, US
Contact	Kim Tompkins
510(k) history	1 submissions · 1 cleared · 2024-2024

CLINICAL EVIDENCE - NCT05920278

Accuracy of Pulse Oximeters in Profound Hypoxia

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	11 patients (actual)
Study sites	1 site
Condition studied	Hypoxia
Study type	Observational
Completion date	Oct 27, 2022
Sponsor	Movano Health (Industry)

Primary outcome**RMSE compared to arterial blood SaO2**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05920278

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