FDA 510(k) Premarket Notification

CLEARED

K220351 Polso Watch

Nov 18, 2022
284 days to decision

K220351 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k220351/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Feb 7, 2022
Decision date	Nov 18, 2022
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Chronisense Medical, Ltd.**
Location	Yokneam Illit, IL
Contact	Bridget Ross
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03735329

Polso SpO2 Accuracy Validation Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	10 patients (actual)
Study sites	1 site
Condition studied	Hypoxia
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 4, 2019
Sponsor	ChroniSense Medical Ltd. (Industry)

Primary outcome

SpO2 percentage

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03735329