FDA 510(k) Premarket Notification

K240305 ANNE Limb

CLEARED

May 28, 2024
116 days to decision

K240305 · Product code: **DQA** · Cardiovascular
Source: https://www.510kdatabase.net/k240305/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Feb 2, 2024
Decision date	May 28, 2024
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sibel Health, Inc.**
Location	Chicago, IL, US
Contact	Sarah Coughlin
510(k) history	5 submissions · 5 cleared · 2023-2026

CLINICAL EVIDENCE - NCT05693168

Accuracy of Pulse Oximeter With Profound Hypoxia

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	12 patients (actual)
Study sites	1 site
Condition studied	Hypoxia
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 24, 2021
Sponsor	Sibel Health Inc. (Industry)

Primary outcome

ARMS of SpO2 Measurements with ANNE Limb compared to SaO2

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05693168