

**K240305 ANNE Limb**May 28, 2024  
116 days to decisionK240305 · Product code: **DQA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k240305/>**SUBMISSION DETAILS**

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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**

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Company	<b>Sibel Health, Inc.</b>
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**

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Status	Completed - <i>No results published to ClinicalTrials.gov</i>
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](https://clinicaltrials.gov/study/NCT05693168)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240305/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov/)), ClinicalTrials.gov (U.S. National Library of Medicine).  
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