

K200537 OxxiomJul 3, 2020
122 days to decisionK200537 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k200537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Mar 3, 2020
Decision date	Jul 3, 2020
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	True Wearables, Inc.
Location	Rancho Santa Margarita, CA, US
Contact	Marcelo Lamego
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Gardner Law PLLC
Contact	Amy Fowler

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

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