

K201468 Pulse OximeterJan 25, 2021
237 days to decisionK201468 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k201468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 2, 2020
Decision date	Jan 25, 2021
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Creative Industry Co., Ltd.
Location	Flintville, TN, US
Contact	Jia Wang
510(k) history	11 submissions · 11 cleared · 2007-2021

REGULATORY CONSULTANT

Consulting firm	International Regulatory Consultants (Irc)
Contact	Charles Mack

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

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