

K201360 Reusable and Disposable SpO2 SensorsAug 19, 2020
90 days to decisionK201360 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k201360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 21, 2020
Decision date	Aug 19, 2020
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xinkang Medical Instrument Co. , Ltd.
Location	Shenzhen, CN
Contact	Xu Changsheng
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	James Tsai

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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