

K191279 Disposable SpO2 SensorDec 6, 2019
207 days to decisionK191279 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k191279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 13, 2019
Decision date	Dec 6, 2019
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Caremed Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Alan Xie
510(k) history	6 submissions · 6 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Chonconn Medical Device Consulting Co., Ltd.
Contact	Kevin Wang

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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