

K173368 Reusable & Disposable SpO2 SensorsAug 31, 2018
309 days to decisionK173368 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k173368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Oct 26, 2017
Decision date	Aug 31, 2018
Days to decision	309 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Coreray Technology, Ltd.
Location	Shenzhen, CN
Contact	Simon Fan
510(k) history	3 submissions · 3 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Field Fu

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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