

**K181270 Disposable SpO2 Sensors, Reusable SpO2 Sensors**Sep 7, 2018  
116 days to decisionK181270 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k181270/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 14, 2018
Decision date	Sep 7, 2018
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orantech, Inc.</b>
Location	Shenzhen, CN
Contact	Yunxi Xiong
510(k) history	5 submissions · 5 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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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