

**K221979 Pulse Oximeter (Model C101A2, C101B1, C101A3)**Oct 16, 2022  
103 days to decisionK221979 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k221979/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Jul 5, 2022
Decision date	Oct 16, 2022
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Imdk Medical Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Yuan Xia
510(k) history	6 submissions · 6 cleared · 2018-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle 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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