

**K211632 Pulse Oximeter (FRO-200, FRO-201, FRO-202, FRO-203, FRO-204, FRO-100, FRO-101, FRO-102, FRO-103, FRO-104)**Jan 14, 2022  
232 days to decisionK211632 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k211632/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 27, 2021
Decision date	Jan 14, 2022
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Narig Bio-Medical Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Fei Han
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211632/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026