

**K203854 Pulse Oximeter**Apr 23, 2021  
113 days to decisionK203854 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k203854/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 31, 2020
Decision date	Apr 23, 2021
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Hexin Zondan Medical Equipment Co., Ltd.</b>
Location	Shenzhen, CN
Contact	John Liu
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203854/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026