

**K092727 H100B PULSE OXIMETER**Dec 3, 2009  
90 days to decisionK092727 · Product code: **DQA** · AnesthesiologySource: <https://www.510kdatabase.net/k092727/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 4, 2009
Decision date	Dec 3, 2009
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edan Instruments, Inc.</b>
Location	Shenzhen, CN
Contact	LI FU
Website	<a href="https://www.edan.com.cn">https://www.edan.com.cn</a>
510(k) history	92 submissions · 92 cleared · 2004-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092727/> 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 24, 2026