

**K103584 ENVISEN NELLCOR, BCI, NONIN, CSI, HP/PHILIPS,  
DATEX-OHMEDA COMPATIBLE DISPOSABLE AND REUSABLE  
SPO2 SENSORS**Jun 10, 2011  
185 days to decisionK103584 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k103584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 7, 2010
Decision date	Jun 10, 2011
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Envisen Industry Co. Limited</b>
Location	Egale, WI, US
Contact	STEPHEN H GORSKI
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103584/>; 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