

**K162014 Nellcor Flexible SpO2 Sensor, Nellcor Flexible SpO2 Sensor, Small, Nellcor Flexible SpO2 Sensor, Home Care (same sensor as above, Home Use Guide incl.), Nellcor Flexible SpO2 Sensor, Small, Home Care (same sensor as above, Home Use Guide incl.)**Feb 6, 2017  
200 days to decisionK162014 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k162014/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jul 21, 2016
Decision date	Feb 6, 2017
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bluepoint Medical GmbH &amp; Co. KG</b>
Location	Selmsdorf, DE
Contact	BERND LINDNER
510(k) history	2 submissions · 2 cleared · 2017-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162014/> 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 June 28, 2026