

**K133064 MYSIGN S PULSE OXIMETER, MYSIGN PC
SOFTWARE (OPTIONAL), SOFTTIP LARGE R-3211-31, FINGER
CLIP F-3211-31**May 2, 2014
217 days to decisionK133064 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k133064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 27, 2013
Decision date	May 2, 2014
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Envitec-Wismar GmbH
Location	Egale, WI, US
Contact	STEPHEN GORSKI
510(k) history	9 submissions · 9 cleared · 2000-2014

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