

K153262 PUREtrace™Feb 7, 2017
455 days to decisionK153262 · Product code: **OSP** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k153262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Uterine Electromyographic Monitor (OSP)
Date received	Nov 10, 2015
Decision date	Feb 7, 2017
Days to decision	455 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nemo Healthcare BV
Location	Veldhoven, NL
Contact	Aron Wierds
510(k) history	1 submissions · 1 cleared · 2017-2017

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