

**K111618 AUDX OTOACOUSTIC EMISSIONS MEASUREMENT  
SYSTEM WITH AUDX I/O FUNCTION**Dec 28, 2011  
201 days to decisionK111618 · Product code: **EWO** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k111618/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Jun 10, 2011
Decision date	Dec 28, 2011
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Natus Medical Incorporated</b>
Location	Oakville, Ontario, CA
Contact	CHARLES L MORIN
Website	<a href="http://www.natus.com/">http://www.natus.com/</a>
510(k) history	10 submissions · 10 cleared · 2010-2018

Natus Medical Incorporated develops diagnostic and monitoring devices for neurological, sensory, and newborn care applications. The company operates with a manufacturing facility in Oakville, Ontario, Canada, and serves healthcare providers globally through neurodiagnostic and sensory screening solutions. Natus Medical received FDA 510(k) clearances from total submissions between 2010 and 2018. The company's cleared devices span General Hospital, Neurology, Ear/Nose/Throat, and Ophthalmic categories, including phototherapy systems, hearing screeners, neurophysiology monit...

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