

**K072033 OTODYNAMICS OTOPORT**Nov 13, 2007  
112 days to decisionK072033 · Product code: **EWO** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k072033/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Jul 24, 2007
Decision date	Nov 13, 2007
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Otodynamics, Ltd.</b>
Location	Crofton, MD, US
Contact	CHRISTINA NORRIS
Website	<a href="http://www.otodynamics.com/">http://www.otodynamics.com/</a>
510(k) history	7 submissions · 7 cleared · 1997-2024

Otodynamics, Ltd. specializes in Ear, Nose, Throat diagnostic and screening instruments. Founded in 1988 by the discoverer of Otoacoustic Emissions, the company pioneered OAE screening technology. Otodynamics designs and manufactures Otoacoustic Emissions (OAE) and Auditory Brainstem Response (ABR) instruments for newborn screening, pediatric assessment, clinical audiology, and research applications. The company has received FDA 510(k) clearances from total submissions since 1997. All submissions focus on Ear, Nose, Throat devices. Otodynamics remains active, with the lat...

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