

K143395 Otoport OAE +ABR Advance, Otoport OAE+ABR DP+TE, Otoport OAE+ABR Screener-Otocheck OAE+ABR, Otocheck OAE+ABR LE, Otocheck ABR Screener-Otodynamics ABR Upgrade KitFeb 23, 2015
89 days to decisionK143395 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k143395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Nov 26, 2014
Decision date	Feb 23, 2015
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Otodynamics, Ltd.
Location	Crofton, MD, US
Contact	Julian Rutherford
Website	http://www.otodynamics.com/
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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