

K983352 ILO2088 ENCHOCHECK OR ILO2088 OTOCHECKDec 11, 1998
79 days to decisionK983352 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k983352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Sep 23, 1998
Decision date	Dec 11, 1998
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Otodynamics, Ltd.
Location	Crofton, MD, US
Contact	E.J. Smith
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...
