

K962995 ILO88. OTODYNAMIC ANALYSER, KIT SYSTEM FOR PCJan 10, 1997
162 days to decisionK962995 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k962995/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Aug 1, 1996
Decision date	Jan 10, 1997
Days to decision	162 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Otodynamics, Ltd.
Location	Crofton, MD, US
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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