FDA 510(k) Premarket Notification

K240430 Otoport Pro

CLEARED

Mar 15, 2024
30 days to decision

K240430 · Product code: **EWO** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k240430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Audiometer (EWO)
Date received	Feb 14, 2024
Decision date	Mar 15, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Otodynamics, Ltd.**
Location	Crofton, MD, US
Contact	Daniel Budd
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...

REGULATORY CONSULTANT

Consulting firm	**Rook Quality Systems**
Contact	Chandler Thames

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov