

K113831 PRIMUS HEARING INSTRUMENT TEST UNITApr 19, 2012
114 days to decisionK113831 · Product code: **ETW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k113831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Hearing Aid / Earphone And Analysis Systems (ETW)
Date received	Dec 27, 2011
Decision date	Apr 19, 2012
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Auditdata A/S
Location	Taastrup, DK
Contact	DAN HAUGBOL
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113831/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 14, 2026