

K122028 AURICAL HITOct 23, 2012
105 days to decisionK122028 · Product code: **ETW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k122028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Hearing Aid / Earphone And Analysis Systems (ETW)
Date received	Jul 10, 2012
Decision date	Oct 23, 2012
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gn Otometrics
Location	Schaumburg, IL, US
Contact	DANIEL KAMM
510(k) history	8 submissions · 8 cleared · 2008-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122028/> 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 2, 2026