

K011135 GSI AUDERAJul 26, 2001
104 days to decisionK011135 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k011135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Apr 13, 2001
Decision date	Jul 26, 2001
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nicolet Biomedical
Location	Golden, CO, US
Contact	DAVID W WAGNER
510(k) history	8 submissions · 8 cleared · 1998-2003

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