

K013977 ECHO-SCREEN T, TA, TD, TDA, TCJun 14, 2002
193 days to decisionK013977 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k013977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Dec 3, 2001
Decision date	Jun 14, 2002
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fischer-Zoth Audiologic Systems, Inc.
Location	Riverton, UT, US
Contact	MICHAEL SOERENSEN
510(k) history	2 submissions · 2 cleared · 1998-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013977/> 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 30, 2026