

K936039 ALGO-2 NEWBORN HEARING SCREENERJan 5, 1995
381 days to decisionK936039 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k936039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Dec 20, 1993
Decision date	Jan 5, 1995
Days to decision	381 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Natus Medical, Inc.
Location	San Carlos, CA, US
Contact	ROBERT T STONE
510(k) history	12 submissions · 12 cleared · 1995-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k936039/> 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 20, 2026