

K810473 MK6 ERA SYSTEMApr 29, 1981
65 days to decisionK810473 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k810473/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Feb 23, 1981
Decision date	Apr 29, 1981
Days to decision	65 days
Third-party review	No

APPLICANT

Company	Amplaid USA, Inc.
Location	Mchenry, IL, US
510(k) history	8 submissions · 8 cleared · 1978-1986

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Device record: <https://www.510kdatabase.net/k810473/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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