

K810138 SYNAP-I INFANT SENSORY ASSESSMENT UNITApr 3, 1981
72 days to decisionK810138 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k810138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jan 21, 1981
Decision date	Apr 3, 1981
Days to decision	72 days
Third-party review	No

APPLICANT

Company	Infant Hearing Assessment Foundation
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1981-1981

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Device record: <https://www.510kdatabase.net/k810138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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