

K811158 OMNIMay 27, 1981
29 days to decisionK811158 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k811158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Apr 28, 1981
Decision date	May 27, 1981
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Omni Hearing Systems
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1981-1984

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Device record: <https://www.510kdatabase.net/k811158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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