

K971399 AURIS AE, AURIS TL, AURIS HS, AURIS AC, AURIS MM, AURIS COE, AURIS CICJun 13, 1997
59 days to decisionK971399 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k971399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Apr 15, 1997
Decision date	Jun 13, 1997
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	General Hearing Instruments, Inc.
Location	Roanoke, VA, US
Contact	ROGER P JUNEAU
510(k) history	5 submissions · 5 cleared · 1985-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971399/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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