

K964816 AUDINA 153 BEHIND THE EAR AND AUDINA 158 BEHIND THE EAR

Jan 17, 1997
49 days to decision

K964816 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k964816/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Nov 29, 1996
Decision date	Jan 17, 1997
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Audina Hearing Instrument
Location	Casselberry, FL, US
Contact	FRANK J ROBILOTTA
510(k) history	8 submissions · 8 cleared · 1982-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k964816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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