FDA 510(k) Premarket Notification

K951678 HI SONIC 2000 DIGITAL HEARING INSTRUMENT

CLEARED

Jun 7, 1995
57 days to decision

K951678 · Product code: **LXB** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k951678/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Apr 11, 1995
Decision date	Jun 7, 1995
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hearing Innovations, Inc.**
Location	Washington, DC, US
Contact	JONATHAN S KAHAN
510(k) history	3 submissions · 3 cleared · 1995-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k951678/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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