FDA 510(k) Premarket Notification

K962388 IN THE EAR HEARING AID

CLEARED

Sep 16, 1996
88 days to decision

K962388 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k962388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jun 20, 1996
Decision date	Sep 16, 1996
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Unique Hearing Technology, Inc.**
Location	Crystal, MN, US
Contact	LARRY LERITZ
510(k) history	1 submissions · 1 cleared · 1996-1996