FDA 510(k) Premarket Notification

K893721 LORI-MODEL O, LOW PROFILE IN-THE EAR INSTRUMENT

CLEARED

Sep 8, 1989
114 days to decision

K893721 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k893721/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	May 17, 1989
Decision date	Sep 8, 1989
Days to decision	114 days
Third-party review	No

APPLICANT

Company	**Lori Medical Laboratories, Inc.**
Location	Long Lake, MN, US
Contact	RICHARD R MAAS
510(k) history	8 submissions · 8 cleared · 1989-1997