FDA 510(k) Premarket Notification

K971859 EARCHECK

CLEARED

Aug 18, 1997
90 days to decision

K971859 · Product code: **ETY** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k971859/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Auditory Impedance (ETY)
Date received	May 20, 1997
Decision date	Aug 18, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mdi Instruments, Inc.**
Location	Woburn, MA, US
Contact	SANDRA KIMBALL
510(k) history	2 submissions · 2 cleared · 1997-1997