

K971859 EARCHECKAug 18, 1997
90 days to decisionK971859 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971859/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 5, 2026