

K951255 IMEDGE VIDEO OSTOSCOPE (ANALOG)Apr 13, 1995
41 days to decisionK951255 · Product code: **ERA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k951255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Mar 3, 1995
Decision date	Apr 13, 1995
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Introspect, Inc.
Location	Excelsior, MN, US
Contact	RICHARD C HAWLEY
510(k) history	2 submissions · 2 cleared · 1995-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951255/> 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