

**K950983 IMEDGE DIGITA OTOSCOPE OR DIGITAL VIDEO
OTOSCOPE**Apr 12, 1995
40 days to decisionK950983 · Product code: ERA · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k950983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Mar 3, 1995
Decision date	Apr 12, 1995
Days to decision	40 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/k950983/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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