FDA 510(k) Premarket Notification

K945081 TRANSTYMPANIC ENDOSCOPE

CLEARED

Mar 6, 1995
140 days to decision

K945081 · Product code: **EOB** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k945081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nasopharyngoscope (flexible Or Rigid) (EOB)
Date received	Oct 17, 1994
Decision date	Mar 6, 1995
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Endooptiks, Inc.**
Location	Marlboro, NJ, US
Contact	JIM OHNECK
510(k) history	5 submissions · 5 cleared · 1992-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k945081/ 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 June 23, 2026