

K950913 PERFECT, ENT SET, PRAKTIKANT, DE LUXEMay 12, 1995
78 days to decisionK950913 · Product code: **ERA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k950913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Feb 23, 1995
Decision date	May 12, 1995
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Rudolf Riester GmbH & Co. KG
Location	D-72417 Jungingen, DE
Contact	KARLHEINZ RIESTER
510(k) history	30 submissions · 26 cleared · 1993-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950913/> 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 May 26, 2026