FDA 510(k) Premarket Notification

K925759 UNI I

CLEARED

Jul 26, 1993
255 days to decision

K925759 · Product code: **ERA** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k925759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Nov 13, 1992
Decision date	Jul 26, 1993
Days to decision	255 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