

K983525 GORE REVOX THYROPLASTY IMPLANTDec 10, 1998
63 days to decisionK983525 · Product code: **MIX** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k983525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Oct 8, 1998
Decision date	Dec 10, 1998
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
Contact	JOHN NICHOLSON
Website	http://www.gore.com/
510(k) history	163 submissions · 148 cleared · 1980-2025

W.L. Gore & Associates, Inc. is a global materials science company specializing in advanced medical devices. The company operates with a manufacturing facility in McHenry, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1980. Cardiovascular devices represent a dominant category, including vascular grafts and balloon catheters. Recent clearances also span general surgery, plastic surgery, and gastroenterology applications. The latest FDA 510(k) clearance in 2025 reflects ongoing regulatory activity. W.L. Gore & Associa...
