

K121257 LARYNGEAL ELECTRODEAug 28, 2012
124 days to decisionK121257 · Product code: **ETN** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k121257/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Apr 26, 2012
Decision date	Aug 28, 2012
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Technomed Europe
Location	Kerkrade, NL
Contact	PIERRE VREULS
510(k) history	12 submissions · 12 cleared · 1999-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121257/> 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 14, 2026