

K990100 POLYMEDIC UPA NERVE STIMULATION NEEDLEAug 2, 2000
576 days to decisionK990100 · Product code: **GXZ** · Neurology
Source: <https://www.510kdatabase.net/k990100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle (GXZ)
Date received	Jan 4, 1999
Decision date	Aug 2, 2000
Days to decision	576 days
Third-party review	No
Summary / Statement	Statement
Other names	POLYMEDIC UPC NERVE STIMULATION NEEDLE

APPLICANT

Company	Te ME NA S.A.R.L.
Location	New Port Riche, FL, US
Contact	JOE HARMS
510(k) history	5 submissions · 5 cleared · 1999-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990100/> 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 25, 2026