

K042375 SMK, CX, CXE, RCNOct 26, 2004
55 days to decisionK042375 · Product code: **GXI** · Neurology
Source: <https://www.510kdatabase.net/k042375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Radiofrequency Lesion (GXI)
Date received	Sep 1, 2004
Decision date	Oct 26, 2004
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042375/> 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