FDA 510(k) Premarket Notification

K042375 SMK, CX, CXE, RCN

CLEARED

Oct 26, 2004
55 days to decision

K042375 · 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