

**K241045 Disposable Subdermal Needle Electrode, Corkscrew**Dec 11, 2024  
238 days to decisionK241045 · Product code: **GXZ** · Neurology  
Source: <https://www.510kdatabase.net/k241045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle (GXZ)
Date received	Apr 17, 2024
Decision date	Dec 11, 2024
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Technomed Europe</b>
Location	Kerkrade, NL
Contact	Sanne Habets
510(k) history	12 submissions · 12 cleared · 1999-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241045/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026