

**K231691 Phantom XL Insulated Dilators**Jun 29, 2023  
20 days to decisionK231691 · Product code: **GXZ** · Neurology  
Source: <https://www.510kdatabase.net/k231691/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Needle (GXZ)
Date received	Jun 9, 2023
Decision date	Jun 29, 2023
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>TeDan Surgical Innovations, Inc.</b>
Location	Sugar Land, TX, US
Contact	Lynne Davies
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231691/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026