

**K021477 PRECLUDE MVP DURA SUBSTITUTE**Nov 8, 2002  
184 days to decisionK021477 · Product code: **GXQ** · Neurology  
Source: <https://www.510kdatabase.net/k021477/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	May 8, 2002
Decision date	Nov 8, 2002
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	Mchenry, IL, US
Contact	TIMOTHY J RYNN
Website	<a href="http://www.gore.com/">http://www.gore.com/</a>
510(k) history	163 submissions · 148 cleared · 1980-2025

W.L. Gore & Associates, Inc. is a global materials science company specializing in advanced medical devices. The company operates with a manufacturing facility in McHenry, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1980. Cardiovascular devices represent a dominant category, including vascular grafts and balloon catheters. Recent clearances also span general surgery, plastic surgery, and gastroenterology applications. The latest FDA 510(k) clearance in 2025 reflects ongoing regulatory activity. W.L. Gore & Associa...

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