

**K023679 GORE 3.0T TORSO ARRAY**Nov 18, 2002  
17 days to decisionK023679 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k023679/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 1, 2002
Decision date	Nov 18, 2002
Days to decision	17 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	Mchenry, IL, US
Contact	TRACY WOLF
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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