

**K960532 PRECLUDE IMA SLEEVE**May 23, 1996  
106 days to decisionK960532 · Product code: **MFX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k960532/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vessel Guard Or Cover, To Facilitate Revision Surgeries (MFX)
Date received	Feb 7, 1996
Decision date	May 23, 1996
Days to decision	106 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	R. LARRY PRATT
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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