

**K940327 INTERVENT ALLERGEN EXCLUSION TECHNOLOGY,
INTERVENT BEDDING SYSTEM, INTERVENT MATTRESS
INTERLINER, INTERVIEW PILLOW**Feb 25, 1994
32 days to decisionK940327 · Product code: **FMW** · General Hospital
Source: <https://www.510kdatabase.net/k940327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Mattress (medical Purposes) (FMW)
Date received	Jan 24, 1994
Decision date	Feb 25, 1994
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
Contact	DAWN LOPEZ
Website	http://www.gore.com/
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...