FDA 510(k) Premarket Notification

K953969 PRECLUDE DURA SUBSTITUTE

CLEARED

Nov 1, 1995
71 days to decision

K953969 · Product code: **GXQ** · Neurology
Source: https://www.510kdatabase.net/k953969/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Aug 22, 1995
Decision date	Nov 1, 1995
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**W.L. Gore & Associates, Inc.**
Location	Mchenry, IL, US
Contact	JOHN NICHOLSON
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...

510k Database - www.510kdatabase.net
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