FDA 510(k) Premarket Notification

K250410 GORE® Tri-Lobe Balloon Catheter

CLEARED

Jun 2, 2025
109 days to decision

K250410 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k250410/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 13, 2025
Decision date	Jun 2, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**W.L. Gore & Associates, Inc.**
Location	Mchenry, IL, US
Contact	Erika Grecco
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...