FDA 510(k) Premarket Notification

K033670 GORE TRI-LOBE BALLOON CATHETER

CLEARED

May 5, 2004
163 days to decision

K033670 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k033670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Nov 24, 2003
Decision date	May 5, 2004
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**W.L. Gore & Associates, Inc.**
Location	Mchenry, IL, US
Contact	BRANDON HANSEN
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...