

K172567 GORE Molding and Occlusion Balloon CatheterJan 31, 2018
159 days to decisionK172567 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k172567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Aug 25, 2017
Decision date	Jan 31, 2018
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W. L. Gore and Associates, Inc.
Location	Phoenix, AZ, US
Contact	Jeremiah Andrews
Website	http://www.gore.com/
510(k) history	3 submissions · 3 cleared · 2018-2022

W. L. Gore and Associates, Inc. is a medical device manufacturer with a manufacturing facility in Phoenix, US. The company specializes in cardiovascular and surgical devices. The company has received FDA 510(k) clearances from total submissions between 2018 and 2022. Its cleared devices focus primarily on cardiovascular applications, including catheter systems and biomaterials for general and plastic surgery. This regulatory record reflects the company's historical activity in the medical device sector. Notable cleared devices include catheter systems designed for cardiov...
