

K123609 MERIT HYDROPHILIC GUIDE WIREJan 16, 2013
56 days to decisionK123609 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k123609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 21, 2012
Decision date	Jan 16, 2013
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems, Inc.
Location	South Jordan, UT, US
Contact	STEPHANIE ERSKINE
Website	https://www.merit.com
510(k) history	178 submissions · 170 cleared · 1988-2026

Merit Medical Systems, Inc. is a leading manufacturer of disposable medical devices for interventional, diagnostic, and therapeutic procedures. Based in South Jordan, the company serves hospitals and physicians worldwide. Merit Medical has established a strong FDA 510(k) regulatory record since its first clearance in 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances span cardiovascular devices, neurology, gastroenterology, and general surgery, demonstrating broad clinical expertise. The latest clearance in 2026 confirms the com...
