FDA 510(k) Premarket Notification

K120644 MERIT HYDROPHILIC GUIDE WIRE

CLEARED

Sep 19, 2012
201 days to decision

K120644 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k120644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 2, 2012
Decision date	Sep 19, 2012
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Merit Medical Systems, Inc.**
Location	South Jordan, UT, US
Contact	MARK MULLANEY
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...