FDA 510(k) Premarket Notification

K230418 Mighty Wire Guide Wire

CLEARED

Oct 28, 2023
254 days to decision

K230418 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k230418/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Feb 16, 2023
Decision date	Oct 28, 2023
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Merit Medical Systems, Inc.**
Location	South Jordan, UT, US
Contact	James Kenny
Website	https://www.merit.com
510(k) history	177 submissions · 169 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...

REGULATORY CONSULTANT

Consulting firm	**Merit Medical Ireland, Ltd.**
Contact	James Kenny

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov