FDA 510(k) Premarket Notification

CLEARED

K241521 Prelude Small O.D. Introducer Guide Wire

Dec 10, 2024
195 days to decision

K241521 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k241521/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 29, 2024
Decision date	Dec 10, 2024
Days to decision	195 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