

K261640 Merit MAK Nitinol/Gold-Tungsten Guide Wire

Jul 13, 2026
56 days to decision

K261640 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k261640/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 18, 2026
Decision date	Jul 13, 2026
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Ireland, Ltd.
Location	South Jordan, UT, US
Contact	Siobhan King
510(k) history	6 submissions · 6 cleared · 2012-2026