

K240859 Glidewire GT-RAug 21, 2024
146 days to decisionK240859 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k240859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 28, 2024
Decision date	Aug 21, 2024
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corporation
Location	Shibuya-Ku, Tokyo, JP
Contact	Qing Liu
510(k) history	13 submissions · 13 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Terumo Medical Corporation
Contact	Qing Liu

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

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