

**K240460 FMD Peripheral Guide Wire F-18 Flex 400  
(CSU415400259)**Jun 13, 2024  
118 days to decisionK240460 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k240460/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Feb 16, 2024
Decision date	Jun 13, 2024
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>FMD Co., Ltd.</b>
Location	Shibuya-Ku, JP
Contact	Higashikubo Takashi
510(k) history	3 submissions · 3 cleared · 2022-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240460/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026