

**K212268 FMD Peripheral Guide Wires F-14 and F-18, FMD Guide Wire Extension F-14 EXT**May 27, 2022  
311 days to decisionK212268 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k212268/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 20, 2021
Decision date	May 27, 2022
Days to decision	311 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>FMD Co., Ltd.</b>
Location	Shibuya-Ku, JP
Contact	Takashi Higashikubo
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/k212268/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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