

K212615 EpiFaith CVSep 21, 2022
399 days to decisionK212615 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k212615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 18, 2021
Decision date	Sep 21, 2022
Days to decision	399 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Flat Medical Co., Ltd.
Location	Taipei, TW
Contact	Tseng Shao Wei
510(k) history	3 submissions · 3 cleared · 2019-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212615/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026