FDA 510(k) Premarket Notification

K212615 EpiFaith CV

CLEARED

Sep 21, 2022
399 days to decision

K212615 · Product code: **DQX** · Cardiovascular
Source: 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