

K222023 RayFlowApr 6, 2023
269 days to decisionK222023 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k222023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 11, 2022
Decision date	Apr 6, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hexacath
Location	Rueil Malmaison, FR
Contact	Anthony Mollieux
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Vaibhav Arvind Rajal

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

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