

K231044 R2P NavicrossJul 27, 2023
106 days to decisionK231044 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k231044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 12, 2023
Decision date	Jul 27, 2023
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Corporation
Location	Elkton, MD, US
Contact	Sandeep Chiplonkar
510(k) history	14 submissions · 14 cleared · 2011-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231044/> 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 13, 2026