FDA 510(k) Premarket Notification

K231044 R2P Navicross

CLEARED

Jul 27, 2023
106 days to decision

K231044 · 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