FDA 510(k) Premarket Notification

K173799 NaviCross 0.018

CLEARED

Mar 29, 2018
105 days to decision

K173799 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k173799/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 14, 2017
Decision date	Mar 29, 2018
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Corporation**
Location	Shibuya-Ku, Tokyo, JP
Contact	Yuko Watanabe
510(k) history	13 submissions · 13 cleared · 2012-2026