FDA 510(k) Premarket Notification

CLEARED

K230156 5F Launcher Guide Catheter, 6F Launcher Guide Catheter, 7F Launcher Guide Catheter, 8F Launcher Guide Catheter

Jun 30, 2023
162 days to decision

K230156 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k230156/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 19, 2023
Decision date	Jun 30, 2023
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	Shalin Parikh
510(k) history	475 submissions · 453 cleared · 1977-2023