FDA 510(k) Premarket Notification

K232570 Steerant™ Super Stiff Guidewire

CLEARED

Oct 24, 2023
61 days to decision

K232570 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k232570/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 24, 2023
Decision date	Oct 24, 2023
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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