FDA 510(k) Premarket Notification

K240885 Shadow Catheter

CLEARED

Dec 19, 2024
262 days to decision

K240885 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k240885/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 1, 2024
Decision date	Dec 19, 2024
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Simpson Interventions, Inc.**
Location	Campbell, CA, US
Contact	Chan Kin
510(k) history	1 submissions · 1 cleared · 2024-2024