FDA 510(k) Premarket Notification

K233350 SINC Support Catheter

CLEARED

Feb 8, 2024
132 days to decision

K233350 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k233350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 29, 2023
Decision date	Feb 8, 2024
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Reflow Medical, Inc.**
Location	San Clemente, CA, US
Contact	Lori Grace
510(k) history	9 submissions · 8 cleared · 2016-2025