FDA 510(k) Premarket Notification

K213666 NuCath Wedge Pressure Catheter

CLEARED

Oct 6, 2022
318 days to decision

K213666 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k213666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Nov 22, 2021
Decision date	Oct 6, 2022
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pfm Medical, Inc.**
Location	Oceanside, CA, US
Contact	Jessica Jho
510(k) history	20 submissions · 17 cleared · 2004-2025