FDA 510(k) Premarket Notification

K214060 LANDMARK REBOA Catheter

CLEARED

Sep 19, 2022
266 days to decision

K214060 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k214060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 27, 2021
Decision date	Sep 19, 2022
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zien Medical Technologies, Inc.**
Location	Salt Lake City, UT, US
Contact	Tim Nieman
510(k) history	2 submissions · 2 cleared · 2022-2024