

K214060 LANDMARK REBOA CatheterSep 19, 2022
266 days to decisionK214060 · Product code: **MJN** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k214060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026