FDA 510(k) Premarket Notification

CLEARED

K220780 ROVO Mechanical Thrombectomy Device

Mar 31, 2023
379 days to decision

K220780 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k220780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Mar 17, 2022
Decision date	Mar 31, 2023
Days to decision	379 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**2mg, Inc.**
Location	Suttons Bay, MI, US
Contact	Ted Karmon
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Tech2med, LLC**
Contact	Kelli Anderson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov