FDA 510(k) Premarket Notification

K231179 Slinky Catheter

CLEARED

Dec 1, 2023
219 days to decision

K231179 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k231179/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Apr 26, 2023
Decision date	Dec 1, 2023
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anoxia Medical, Inc.**
Location	Hayward, CA, US
Contact	Henry Nita
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**ProMedoss, Inc.**
Contact	Bosmat Friedman

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