FDA 510(k) Premarket Notification

K232831 Quiver Aspiration Pump

CLEARED

Feb 22, 2024
162 days to decision

K232831 · Product code: **BTA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232831/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Sep 13, 2023
Decision date	Feb 22, 2024
Days to decision	162 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-Cox

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