FDA 510(k) Premarket Notification

K233403 Flexset System

CLEARED

Apr 30, 2024
209 days to decision

K233403 · Product code: **GWQ** · Neurology
Source: https://www.510kdatabase.net/k233403/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Oct 4, 2023
Decision date	Apr 30, 2024
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zeto, Inc.**
Location	Raleigh, NC, US
Contact	Aswin Gunasekar
510(k) history	3 submissions · 3 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Mary Vater

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