FDA 510(k) Premarket Notification

K232210 X-trodes System M

CLEARED

Feb 4, 2024
193 days to decision

K232210 · Product code: **GWL** · Neurology
Source: https://www.510kdatabase.net/k232210/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Jul 26, 2023
Decision date	Feb 4, 2024
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**X-Trodes**
Location	Herzeliya, IL
Contact	Ziv Peremen
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Biologics Consulting Group**
Contact	Donna-Bea Tillman

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