FDA 510(k) Premarket Notification

K230506 PureLift Pro Edition

CLEARED

Jun 21, 2023
117 days to decision

K230506 · Product code: **NFO** · Neurology
Source: https://www.510kdatabase.net/k230506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Feb 24, 2023
Decision date	Jun 21, 2023
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xtreem Pulse**
Location	New York, NY, US
Contact	Andrew Barile
510(k) history	1 submissions · 1 cleared · 2023-2023