FDA 510(k) Premarket Notification

K244030 Needle Stimulator (CMNS6-1 PLUS, CMNS6-3)

CLEARED

Mar 28, 2025
88 days to decision

K244030 · Product code: **BWK** · Neurology
Source: https://www.510kdatabase.net/k244030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electro-acupuncture (BWK)
Date received	Dec 30, 2024
Decision date	Mar 28, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wuxi Jiajian Medical Instrument Co., Ltd.**
Location	Wuxi, CN
Contact	Wenqing Wang
510(k) history	12 submissions · 12 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	**Shanghai CV Technology Co., Ltd.**
Contact	Doris Dong

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