FDA 510(k) Premarket Notification

K233322 Mochida Nerve Cuff

CLEARED

Jun 21, 2024
266 days to decision

K233322 · Product code: **JXI** · Neurology
Source: https://www.510kdatabase.net/k233322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Nerve (JXI)
Date received	Sep 29, 2023
Decision date	Jun 21, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mochida Pharmaceutical Co., Ltd.**
Location	Walker, MI, US
Contact	Akiko Koarai
Website	http://www.mochida.co.jp
510(k) history	4 submissions · 4 cleared · 1984-2024

Mochida Pharmaceutical Co., Ltd. is a Japanese pharmaceutical and medical device manufacturer with a manufacturing facility in Walker, US. The company develops and markets medical devices across multiple therapeutic areas, including surgical and healthcare solutions. Mochida has received FDA 510(k) clearances from total submissions, with a dominant focus on General & Plastic Surgery devices. The company's regulatory history spans from 1984 to 2024, demonstrating sustained engagement with FDA clearance pathways. Recent cleared devices include laser systems for surgical app...

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Kelliann H. Payne

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