FDA 510(k) Premarket Notification

K013399 MODEL MES-9000/EMG SYSTEM

CLEARED

Nov 13, 2001
29 days to decision

K013399 · Product code: **HCC** · Neurology
Source: https://www.510kdatabase.net/k013399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Biofeedback (HCC)
Date received	Oct 15, 2001
Decision date	Nov 13, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Myotronics-Noromed, Inc.**
Location	Tukwila, WA, US
Contact	FRAY ADIB
510(k) history	7 submissions · 7 cleared · 1999-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k013399/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026