FDA 510(k) Premarket Notification

K992439 NORODYN 8000 SEMG SYSTEM, ND-8000

CLEARED

Aug 13, 1999
22 days to decision

K992439 · Product code: **HCC** · Neurology
Source: https://www.510kdatabase.net/k992439/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Biofeedback (HCC)
Date received	Jul 22, 1999
Decision date	Aug 13, 1999
Days to decision	22 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