FDA 510(k) Premarket Notification

K011430 ACTIWARE-PLMS

CLEARED

May 31, 2001
22 days to decision

K011430 · Product code: **GWQ** · Neurology
Source: https://www.510kdatabase.net/k011430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	May 9, 2001
Decision date	May 31, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mini-Mitter Co., Inc.**
Location	Bend, OR, US
Contact	JACK E MCKENZIE
510(k) history	5 submissions · 5 cleared · 1999-2004