FDA 510(k) Premarket Notification

K884537 AE-800PA EEG MODULE

CLEARED

Dec 29, 1988
62 days to decision

K884537 · Product code: **GWQ** · Neurology
Source: https://www.510kdatabase.net/k884537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Oct 28, 1988
Decision date	Dec 29, 1988
Days to decision	62 days
Third-party review	No

APPLICANT

Company	**Nihon Kohden America, Inc.**
Location	Foothill Ranch, CA, US
Contact	MIKE DASHEFSKY
510(k) history	166 submissions · 163 cleared · 1979-2012