FDA 510(k) Premarket Notification

K962157 MODEL 1310 NEUROLINK NEUROMONITORING SYSTEM

CLEARED

Nov 25, 1996
174 days to decision

K962157 · Product code: **GWQ** · Neurology
Source: https://www.510kdatabase.net/k962157/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Jun 4, 1996
Decision date	Nov 25, 1996
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Physiometrix, Inc.**
Location	Sunnyvale, CA, US
Contact	DAWN E FRAZER
510(k) history	22 submissions · 22 cleared · 1992-2005