FDA 510(k) Premarket Notification

K932571 TOMEY PE-400 PORTABLE ERG & VEP WITH OPTIONAL PS-4

CLEARED

Aug 31, 1995
826 days to decision

K932571 · Product code: **GWE** · Neurology
Source: https://www.510kdatabase.net/k932571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	May 27, 1993
Decision date	Aug 31, 1995
Days to decision	826 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Tomey Corporation USA**
Location	Cambridge, MA, US
Contact	LORI TRUITT
510(k) history	9 submissions · 9 cleared · 1991-1997