

**K932571 TOMEY PE-400 PORTABLE ERG & VEP WITH
OPTIONAL PS-4**Aug 31, 1995
826 days to decisionK932571 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k932571/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026