FDA 510(k) Premarket Notification

K862231 EMPI, MODEL 1000 HAND HELD ELECTRODE

CLEARED

Aug 27, 1986
77 days to decision

K862231 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k862231/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jun 11, 1986
Decision date	Aug 27, 1986
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**Empi**
Location	Walker, MI, US
Contact	GEORGE E MATHIESEN
Website	http://www.empik.com
510(k) history	60 submissions · 56 cleared · 1977-2010

Empi is a historical medical device manufacturer based in Walker, US. The company specialized in electrotherapy and neurostimulation devices. Empi received FDA 510(k) clearances from total submissions between 1977 and 2010. The company's primary focus was physical medicine and neurology devices, including transcutaneous nerve stimulators, iontophoresis systems, and electrotherapy equipment. This regulatory record spans over three decades of device development and market clearance. Empi is now a historical record only, with no FDA 510(k) clearances issued in more than 13 y...