FDA 510(k) Premarket Notification

K896485 MODIFIED ISLAND TENS DISP. ELECTRODE FOR SNAP CONN

CLEARED

Dec 21, 1989
38 days to decision

K896485 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k896485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Nov 13, 1989
Decision date	Dec 21, 1989
Days to decision	38 days
Third-party review	No

APPLICANT

Company	**Empi**
Location	Walker, MI, US
Contact	STACY MATTSON
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...