FDA 510(k) Premarket Notification

K800380 FES ORTHOSIS MODEL NO. 2000

CLEARED

Mar 17, 1980
24 days to decision

K800380 · Product code: **GZI** · Neurology
Source: https://www.510kdatabase.net/k800380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Feb 22, 1980
Decision date	Mar 17, 1980
Days to decision	24 days
Third-party review	No

APPLICANT

Company	**Empi**
Location	Walker, MI, US
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...