FDA 510(k) Premarket Notification

K951951 FOCUS MODEL 795 UNIT

CLEARED

May 17, 1996
387 days to decision

K951951 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k951951/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Apr 26, 1995
Decision date	May 17, 1996
Days to decision	387 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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