

**K021100 300 PV COMPLETE ELECTROTHERAPY SYSTEM**Jun 18, 2002  
75 days to decisionK021100 · Product code: **IPF** · Physical Medicine  
Source: <https://www.510kdatabase.net/k021100/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Apr 4, 2002
Decision date	Jun 18, 2002
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Empi</b>
Location	Walker, MI, US
Contact	SHEILA HEMEON-HEYER
Website	<a href="http://www.empik.com">http://www.empik.com</a>
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...

---