

**K970307 MINNOVA PELVIC FLOOR STIMULATION SYSTEM**Apr 22, 1997  
85 days to decisionK970307 · Product code: **KPI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k970307/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jan 27, 1997
Decision date	Apr 22, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Empi</b>
Location	Walker, MI, US
Contact	CAROLYN M STEELE HUSTEN
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...

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