

**K964577 INNOVA COMFORTPULSE VAGINAL ELECTRODE
(199204)/INNOVA COMFORTPULSE SMALL VAGINAL
ELECTRODE(199205)**Jan 24, 1997
71 days to decisionK964577 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k964577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Nov 14, 1996
Decision date	Jan 24, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Empi
Location	Walker, MI, US
Contact	CAROLYN M STEELE HUSTEN
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...