FDA 510(k) Premarket Notification

K983206 SMALL VAGINAL/RECTAL ELECTRODE

CLEARED

Nov 3, 1998
50 days to decision

K983206 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k983206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Sep 14, 1998
Decision date	Nov 3, 1998
Days to decision	50 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...