FDA 510(k) Premarket Notification

K954272 INNOVA RECTAL STIMULATON ELECTRODE

CLEARED

Apr 15, 1996
216 days to decision

K954272 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k954272/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Sep 12, 1995
Decision date	Apr 15, 1996
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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