FDA 510(k) Premarket Notification

CLEARED

K072946 HYBRESIS IONTOPHORESIS DRUG DELIVERY SYSTEM

Nov 16, 2007
30 days to decision

K072946 · Product code: **EGJ** · Physical Medicine
Source: https://www.510kdatabase.net/k072946/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Iontophoresis, Other Uses (EGJ)
Date received	Oct 17, 2007
Decision date	Nov 16, 2007
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Empi**
Location	Walker, MI, US
Contact	SANDRA WALROD
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...