FDA 510(k) Premarket Notification

**CLEARED**

# K912015 TBD, EMPI BUFFERED IONTOPHORESIS ELECTRODED MDL. 3

Nov 15, 1991
193 days to decision

K912015 · Product code: **EGJ** · Physical Medicine
Source: https://www.510kdatabase.net/k912015/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Iontophoresis, Other Uses (EGJ) |
| Date received | May 6, 1991 |
| Decision date | Nov 15, 1991 |
| Days to decision | 193 days |
| Third-party review | No |
| Summary / Statement | Statement |

## 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...