

K182363 BTL-703Jan 24, 2019
147 days to decisionK182363 · Product code: **IMJ** · Physical Medicine
Source: <https://www.510kdatabase.net/k182363/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat (IMJ) |
| Date received | Aug 30, 2018 |
| Decision date | Jan 24, 2019 |
| Days to decision | 147 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | BTL Industries, Inc. |
| Location | Malborough, MA, US |
| Contact | David Chmel |
| Website | https://www.btl.net.com |
| 510(k) history | 41 submissions · 41 cleared · 2010-2026 |

BTL Industries, Inc. is a medical device manufacturer based in Marlborough, US. The company develops therapeutic and rehabilitation technologies across multiple clinical specialties. BTL Industries has received FDA 510(k) clearances from total submissions since its first clearance in 2010. The company maintains active regulatory status, with its most recent clearance in 2026. Device clearances span General & Plastic Surgery, Physical Medicine, Dental, Neurology, and Gastroenterology & Urology specialties. The company's product portfolio includes robotic rehabilitation sys...