

**K252963 BTL-899TT**Jun 12, 2026  
268 days to decisionK252963 · Product code: **IMJ** · Physical Medicine  
Source: <https://www.510kdatabase.net/k252963/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat (IMJ)
Date received	Sep 17, 2025
Decision date	Jun 12, 2026
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BTL Industries, Inc.</b>
Location	Malborough, MA, US
Contact	David Chmel
Website	<a href="https://www.btlnet.com">https://www.btlnet.com</a>
510(k) history	42 submissions · 42 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...

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