

K150353 BTL-4000Nov 13, 2015
275 days to decisionK150353 · Product code: **IMG** · Physical Medicine
Source: <https://www.510kdatabase.net/k150353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Ultrasound And Muscle, For Use In Applying Therapeutic Deep Heat (IMG)
Date received	Feb 11, 2015
Decision date	Nov 13, 2015
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	BTL Industries, Inc.
Location	Malborough, MA, US
Contact	Jan Zarsky
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...