

K161551 TR-100Sep 13, 2016
102 days to decisionK161551 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Jun 3, 2016
Decision date	Sep 13, 2016
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	BTL Industries, Inc.
Location	Malborough, MA, US
Contact	Jan Zarsky
Website	https://www.btlnet.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...

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