

**K180813 BTL 799-2**Jun 14, 2018  
77 days to decisionK180813 · Product code: **NGX** · Physical Medicine  
Source: <https://www.510kdatabase.net/k180813/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Mar 29, 2018
Decision date	Jun 14, 2018
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	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.btl.net.com">https://www.btl.net.com</a>
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...