

**K163165 AM-100**Feb 16, 2017  
98 days to decisionK163165 · Product code: **NGX** · Physical Medicine  
Source: <https://www.510kdatabase.net/k163165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Nov 10, 2016
Decision date	Feb 16, 2017
Days to decision	98 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...