

K241516 BTL-398Feb 10, 2025
257 days to decisionK241516 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	May 29, 2024
Decision date	Feb 10, 2025
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	BTL Industries, Inc.
Location	Malborough, MA, US
Contact	David Chmel
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...

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Device record: <https://www.510kdatabase.net/k241516/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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