FDA 510(k) Premarket Notification

K162010 HPM-6000U

CLEARED

Dec 13, 2016
146 days to decision

K162010 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k162010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jul 20, 2016
Decision date	Dec 13, 2016
Days to decision	146 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...