FDA 510(k) Premarket Notification

CLEARED

K100310 BTL-08 ECG RECORDER MODEL BTL-08 ECG LC PLUS, BTL-08 ECG LT PLUS

Oct 13, 2010
252 days to decision

K100310 · Product code: **MWJ** · Cardiovascular
Source: https://www.510kdatabase.net/k100310/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Feb 3, 2010
Decision date	Oct 13, 2010
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**BTL Industries, Inc.**
Location	Malborough, MA, US
Contact	RICHARD VINCINS, CQA, RAC (US,EU)
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...