FDA 510(k) Premarket Notification

K143559 XP1000 RF

CLEARED

Jun 11, 2015
177 days to decision

K143559 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k143559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 16, 2014
Decision date	Jun 11, 2015
Days to decision	177 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...