

**K152731 XP1100 RF**Jul 20, 2016  
302 days to decisionK152731 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k152731/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 22, 2015
Decision date	Jul 20, 2016
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BTL Industries, Inc.</b>
Location	Malborough, MA, US
Contact	JAN ZARSKY
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...