

**K163176 Exilis XP II**Jan 12, 2017  
59 days to decisionK163176 · Product code: **PBX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k163176/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Nov 14, 2016
Decision date	Jan 12, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BTL Industries, Inc.</b>
Location	Malborough, MA, US
Contact	David Chmel
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...

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