

K252561 BTL-754FFFeb 18, 2026
189 days to decisionK252561 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k252561/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Aug 13, 2025 |
| Decision date | Feb 18, 2026 |
| Days to decision | 189 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | BTL Industries, Inc. |
| Location | Malborough, MA, US |
| Contact | Chmel David |
| Website | https://www.btl.net.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...