FDA 510(k) Premarket Notification

K233604 BTL-785S

CLEARED

Mar 28, 2024
140 days to decision

K233604 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233604/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 9, 2023
Decision date	Mar 28, 2024
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**BTL Industries, Inc.**
Location	Malborough, MA, US
Contact	David Chmel
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...

CLINICAL EVIDENCE - NCT05831332

Safety and Efficacy of the BTL-785F Device for Non-invasive Reduction of Submental Fat

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	56 patients (actual)
Study sites	1 site
Condition studied	Skin Laxity
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 25, 2023
Sponsor	BTL Industries Ltd. (Industry)

Primary outcome

Change of submental fat thickness

Secondary outcome

Evaluation the effect on submental skin laxity

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05831332