

**K193201 BTL-785F**Aug 21, 2020  
275 days to decisionK193201 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193201/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 20, 2019
Decision date	Aug 21, 2020
Days to decision	275 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Btl</b>
Location	Malborough, MA, US
Contact	David Chmel
510(k) history	4 submissions · 4 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193201/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026