FDA 510(k) Premarket Notification

# K193201 BTL-785F

**CLEARED**

Aug 21, 2020
275 days to decision

K193201 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k193201/

## SUBMISSION DETAILS

| | |
|---|---|
| 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 | **Btl** |
| Location | Malborough, MA, US |
| Contact | David Chmel |
| 510(k) history | 4 submissions · 4 cleared · 2019-2021 |