

K252150 Ultrasonic Bipolar Generator (USG-410)Oct 7, 2025
90 days to decisionK252150 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 9, 2025
Decision date	Oct 7, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Reuseable Cordless Transducer (TD-410); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 45cm (TB2-0545FC); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 35cm (TB2-0535FC); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 25cm (TB2-0525FC); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 20cm (TB2-0520FC)

APPLICANT

Company	Olympus Medical Systems Corporation
Location	Melville, NY, US
Contact	Norikiyo Shibata
510(k) history	81 submissions · 81 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	Olympus Corporation of the Americas
Contact	Elizabeth Greene

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252150/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026