

K251899 E BlatorOct 1, 2025
103 days to decisionK251899 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 20, 2025
Decision date	Oct 1, 2025
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	New Deantronics Taiwan , Ltd.
Location	Tu Cheng City, TW
Contact	Hung-Kuei Tsai
510(k) history	18 submissions · 18 cleared · 1998-2025

REGULATORY CONSULTANT

Consulting firm	Coombs Medical Device Consulting, Inc.
Contact	Coombs Craig

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/k251899/> 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 14, 2026