FDA 510(k) Premarket Notification

K251899 E Blator

CLEARED

Oct 1, 2025
103 days to decision

K251899 · Product code: **GEI** · General & Plastic Surgery
Source: 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