

K233099 GladiatorMay 22, 2024
239 days to decisionK233099 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233099/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 26, 2023
Decision date	May 22, 2024
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rohrer Aesthetics, LLC
Location	Birmingham, AL, US
Contact	Mark Rohrer
510(k) history	6 submissions · 6 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233099/> 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