FDA 510(k) Premarket Notification

K233099 Gladiator

CLEARED

May 22, 2024
239 days to decision

K233099 · Product code: **GEI** · General & Plastic Surgery
Source: 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