

K192621 Medical RFNov 6, 2020
410 days to decisionK192621 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 23, 2019
Decision date	Nov 6, 2020
Days to decision	410 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Triworks Group Srl
Location	Campobasso, IT
Contact	Elio Piero Berchicci
510(k) history	2 submissions · 2 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192621/> 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 27, 2026