

K210569 Disposable Monopolar Laparoscopic Shafts and Reusable HandlesAug 16, 2021
171 days to decisionK210569 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 26, 2021
Decision date	Aug 16, 2021
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dannik, LLC
Location	Winter Park, FL, US
Contact	Olga Haberland
510(k) history	3 submissions · 3 cleared · 2021-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210569/> 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 26, 2026