

K193018 Surgical Direct Hand-held Laparoscopic InstrumentsDec 20, 2019
52 days to decisionK193018 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193018/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 29, 2019
Decision date	Dec 20, 2019
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Direct, Inc.
Location	Deland, FL, US
Contact	David Murray
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Smith Associates
Contact	E. J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193018/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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