

K193019 DANNIK Disposable Monopolar Laparoscopic Instrument

Mar 4, 2020
127 days to decision

K193019 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k193019/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 29, 2019
Decision date	Mar 4, 2020
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dannik
Location	Winter Park, FL, US
Contact	Olga Haberlad
510(k) history	5 submissions · 5 cleared · 2019-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193019/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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