

**K201063 DANNIK Disposable Monopolar Laparoscopic Instrument**Jun 9, 2020  
49 days to decisionK201063 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201063/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 21, 2020
Decision date	Jun 9, 2020
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201063/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026