

**K203640 CoolSeal Reveal**May 6, 2021  
143 days to decisionK203640 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203640/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 14, 2020
Decision date	May 6, 2021
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bolder Surgical, LLC</b>
Location	Louisville, CO, US
Contact	Nicholas Wong
510(k) history	5 submissions · 5 cleared · 2020-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203640/> 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 May 26, 2026