

**K233185 MODEL P8400 Controller for C2DX's Hemostatix Thermal Scalpel System**Oct 24, 2023  
26 days to decisionK233185 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233185/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 28, 2023
Decision date	Oct 24, 2023
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C2dx, Inc.</b>
Location	Schoolcraft, MI, US
Contact	Brad Beale
510(k) history	1 submissions · 1 cleared · 2023-2023

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233185/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026