

**K223440 Plasma Pen (Plasma MD)**Mar 2, 2023  
108 days to decisionK223440 · Product code: **QVJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k223440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Power Electrosurgical Devices For Skin Lesion Destruction (QVJ)
Date received	Nov 14, 2022
Decision date	Mar 2, 2023
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Plasma Pen (Plasma +)

**APPLICANT**

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Company	<b>Plasma Concepts</b>
Location	Woburn, MA, US
Contact	Brendan Aarons
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medicept, LLC</b>
Contact	Richelle Helman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223440/> 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 27, 2026