

**K253153 SER Pen Carain MicroSystem (MP1209SP)**Oct 29, 2025  
33 days to decisionK253153 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253153/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Microneedle Device (QAI)
Date received	Sep 26, 2025
Decision date	Oct 29, 2025
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Su-Ko Technologies, LLC</b>
Location	Houston, TX, US
Contact	Yuan Yuan "Susie" Su Korrodi
510(k) history	2 submissions · 2 cleared · 2024-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Contract In-House Counsel and Consultants, LLC D/B/A FDA Att</b>
Contact	Marc Sanchez

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/k253153/> 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 13, 2026