

K241355 SER Pen Carain MicroSystem (MP1209SP)Oct 9, 2024
148 days to decisionK241355 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	May 14, 2024
Decision date	Oct 9, 2024
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Contract In-House Counsel and Consultants,
Contact	Marc Sanchez, Esq.

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.netDevice record: <https://www.510kdatabase.net/k241355/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026