FDA 510(k) Premarket Notification

K253153 SER Pen Carain MicroSystem (MP1209SP)

CLEARED

Oct 29, 2025
33 days to decision

K253153 · Product code: **QAI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253153/

SUBMISSION DETAILS

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

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, LLC D/B/A FDA Att**
Contact	Marc Sanchez

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov