FDA 510(k) Premarket Notification

K241355 SER Pen Carain MicroSystem (MP1209SP)

CLEARED

Oct 9, 2024
148 days to decision

K241355 · Product code: **QAI** · General & Plastic Surgery
Source: 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