

K253002 SkinStylus SteriLock MicroSystem (MP1209SL)Feb 19, 2026
153 days to decisionK253002 · Product code: **QAI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Sep 19, 2025
Decision date	Feb 19, 2026
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Esthetic Medical, Inc.
Location	Long Beach, CA, US
Contact	Sean Song
510(k) history	2 submissions · 2 cleared · 2023-2026

CLINICAL EVIDENCE - NCT06032286**Evaluation of Efficacy and Safety of the Skinstylus Sterilock Microneedling System for the Treatment of Facial Wrinkles**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	51 patients (actual)
Study sites	2 sites
Condition studied	Subjects Displaying Facial Ageing
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 9, 2024
Sponsor	Beauty Health (Industry)

Primary outcome

Wrinkle improvement

Secondary outcome

Texture and laxity

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06032286