

K252591 Automatic Micro Needle System (CODE-X)May 13, 2026
271 days to decisionK252591 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Aug 15, 2025
Decision date	May 13, 2026
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Woorhi Mechatronics Co., Ltd.
Location	Gunpo-Si, KR
Contact	Jungsu Lee
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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