

K230420 Dr. pen Microneedling SystemAug 11, 2023
176 days to decisionK230420 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Feb 16, 2023
Decision date	Aug 11, 2023
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Ekai Electronic Technology Co., Ltd.
Location	Guangzhou, CN
Contact	Guihua Chen
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	New Risen Enterprise Management Consulting Co.,Ltd
Contact	Helen Nan

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/k230420/> 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 26, 2026