FDA 510(k) Premarket Notification

K230420 Dr. pen Microneedling System

CLEARED

Aug 11, 2023
176 days to decision

K230420 · Product code: **QAI** · General & Plastic Surgery
Source: 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**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov