

K212558 MicroPen EVONov 24, 2021
103 days to decisionK212558 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Aug 13, 2021
Decision date	Nov 24, 2021
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eclipse Medcorp, LLC
Location	The Colony, TX, US
Contact	Julie Summerville
510(k) history	4 submissions · 4 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212558/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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