

**K202243 SkinPen Precision System**Apr 2, 2021  
235 days to decisionK202243 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202243/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Aug 10, 2020
Decision date	Apr 2, 2021
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Crown Aesthetics</b>
Location	Dallas, TX, US
Contact	Marie Fogartie
510(k) history	3 submissions · 3 cleared · 2021-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202243/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026