

**K221011 AI.ME System**Dec 20, 2022  
259 days to decisionK221011 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221011/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Apr 5, 2022
Decision date	Dec 20, 2022
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Venus Concept USA, Inc.</b>
Location	Sunrise, FL, US
Contact	William H McGrail
510(k) history	11 submissions · 11 cleared · 2014-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221011/> 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