

**K250524 Mendaera Guidance System**Jul 2, 2025  
131 days to decisionK250524 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k250524/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Feb 21, 2025
Decision date	Jul 2, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mendaera, Inc.</b>
Location	San Mateo, CA, US
Contact	Josh DeFonzo
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250524/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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