FDA 510(k) Premarket Notification

K250524 Mendaera Guidance System

CLEARED

Jul 2, 2025
131 days to decision

K250524 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k250524/

SUBMISSION DETAILS

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

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