

K221624 Avenda Health AI Prostate Cancer Planning SoftwareNov 22, 2022
169 days to decisionK221624 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k221624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Jun 6, 2022
Decision date	Nov 22, 2022
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avenda Health, Inc.
Location	Santa Monica, CA, US
Contact	Brittany Berry-Pusey
510(k) history	2 submissions · 2 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221624/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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