

K254161 Automated Aortic Stenosis Software (AutoAS)Mar 27, 2026
95 days to decisionK254161 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k254161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Dec 22, 2025
Decision date	Mar 27, 2026
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
Location	Wauwatosa, WI, US
Contact	Tahir Rizvi
510(k) history	14 submissions · 14 cleared · 2016-2026

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