

K251342 EchoPAC Software Only / EchoPAC Plug-inJul 16, 2025
77 days to decisionK251342 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k251342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 30, 2025
Decision date	Jul 16, 2025
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems Ultrasound and Primary Care Diagnostics
Location	Wauwatosa, WI, US
Contact	Lee Bush
510(k) history	64 submissions · 64 cleared · 2015-2026

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