

K220940 EchoPAC Software Only, EchoPAC Plug-inJul 22, 2022
113 days to decisionK220940 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k220940/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | Mar 31, 2022 |
| Decision date | Jul 22, 2022 |
| Days to decision | 113 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 | Tracey Ortiz |
| 510(k) history | 64 submissions · 64 cleared · 2015-2026 |

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