

K252029 AI-CVDDec 19, 2025
172 days to decisionK252029 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252029/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | Jun 30, 2025 |
| Decision date | Dec 19, 2025 |
| Days to decision | 172 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | HeartLung Corporation |
| Location | Torrance, CA, US |
| Contact | Mark Scott |
| 510(k) history | 3 submissions · 3 cleared · 2022-2025 |

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