

K251456 BrightHeart View ClassifierJun 5, 2025
24 days to decisionK251456 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k251456/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | May 12, 2025 |
| Decision date | Jun 5, 2025 |
| Days to decision | 24 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | Yes - Predetermined Change Control Plan (AI/SaMD) |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Brightheart |
| Location | Paris, FR |
| Contact | Christophe Gardella |
| 510(k) history | 5 submissions · 5 cleared · 2024-2025 |

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