

K243684 BrightHeart View ClassifierMay 7, 2025
159 days to decisionK243684 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 29, 2024
Decision date	May 7, 2025
Days to decision	159 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243684/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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