

K251483 SwiftSight-BrainSep 23, 2025
132 days to decisionK251483 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k251483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 14, 2025
Decision date	Sep 23, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Airs Medical, Inc.
Location	Seoul, KR
Contact	Lee HaeRi
510(k) history	5 submissions · 5 cleared · 2021-2026

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