

K253775 SwiftMRMar 26, 2026
120 days to decisionK253775 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k253775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 26, 2025
Decision date	Mar 26, 2026
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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