

K261349 SwiftMR

Jul 24, 2026
91 days to decision

K261349 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k261349/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 24, 2026
Decision date	Jul 24, 2026
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Airs Medical, Inc.
Location	Seoul, KR
Contact	Markus Cho
510(k) history	6 submissions · 6 cleared · 2021-2026