

**K220416 SwiftMR**May 25, 2022  
100 days to decisionK220416 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k220416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 14, 2022
Decision date	May 25, 2022
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Airs Medical, Inc.</b>
Location	Seoul, KR
Contact	Jihyeon Seo
510(k) history	5 submissions · 5 cleared · 2021-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220416/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026