

K230854 SwiftMROct 27, 2023
213 days to decisionK230854 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k230854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 28, 2023
Decision date	Oct 27, 2023
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230854/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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