

K210999 SwiftMROct 14, 2021
195 days to decisionK210999 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k210999/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 2, 2021
Decision date	Oct 14, 2021
Days to decision	195 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

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