

K253008 maiLinkJan 5, 2026
108 days to decisionK253008 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k253008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 19, 2025
Decision date	Jan 5, 2026
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maihub Corp.
Location	Seoul, KR
Contact	Gyungeun Park
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253008/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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