

K250039 HPACSOct 3, 2025
268 days to decisionK250039 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k250039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 8, 2025
Decision date	Oct 3, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Healthhub
Location	Seoul, KR
Contact	SungHyuk Hong
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250039/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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