

K250914 MediAI-BADec 18, 2025
266 days to decisionK250914 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 27, 2025
Decision date	Dec 18, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Crescom Co., Ltd.
Location	Seongnam-Si, KR
Contact	Rosa Han
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250914/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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