

K240353 Hyper Insight - ICHJul 1, 2024
147 days to decisionK240353 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k240353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Feb 5, 2024
Decision date	Jul 1, 2024
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sk, Inc.
Location	Seongnam-Si, KR
Contact	Jeffrey Choi
510(k) history	1 submissions · 1 cleared · 2024-2024

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