

**K233247 Heuron ICH**May 15, 2024  
230 days to decisionK233247 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k233247/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Sep 28, 2023
Decision date	May 15, 2024
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heuron Co., Ltd.</b>
Location	Incheon, KR
Contact	Inah Jeong
510(k) history	5 submissions · 5 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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