

K230209 Sonix HealthOct 20, 2023
268 days to decisionK230209 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k230209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 25, 2023
Decision date	Oct 20, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ontact Health Co., Ltd.
Location	Seoul, KR
Contact	Hyuk-Jae Chang
510(k) history	2 submissions · 2 cleared · 2023-2024

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