

K233676 Us2.v2Apr 1, 2024
137 days to decisionK233676 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k233676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 16, 2023
Decision date	Apr 1, 2024
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eko.Ai Pte Ltd. D/B/A Us2.Ai
Location	Singapore, SG
Contact	Hui Qun Tay
510(k) history	3 submissions · 3 cleared · 2021-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233676/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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