

K193271 uAI EasyTriage-RibJan 15, 2021
416 days to decisionK193271 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k193271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Nov 26, 2019
Decision date	Jan 15, 2021
Days to decision	416 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai United Imaging Intelligence Co., Ltd.
Location	Shanghai, CN
Contact	Zhao Xiaojing
510(k) history	4 submissions · 4 cleared · 2021-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193271/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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