

K213566 ClearRead Xray PneumothoraxMar 10, 2022
121 days to decisionK213566 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k213566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Nov 9, 2021
Decision date	Mar 10, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Riverain Technologies, Inc.
Location	Miamisburg, OH, US
Contact	Jonathan Jackson
510(k) history	3 submissions · 3 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213566/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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