

K220239 Solid State X-ray Imager(Model: FXRD-4386WB)Sep 13, 2022
228 days to decisionK220239 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k220239/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jan 28, 2022
Decision date	Sep 13, 2022
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vieworks Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	Kevin Oh
510(k) history	19 submissions · 19 cleared · 2007-2025

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220239/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026