

K221512 Vivix-S FW (Model: FXRD-2530FAW, FXRD-3643FAW, FXRD-4343FAW)Jul 20, 2022
57 days to decisionK221512 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k221512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 24, 2022
Decision date	Jul 20, 2022
Days to decision	57 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](https://accessdata.fda.gov)

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