FDA 510(k) Premarket Notification

CLEARED

K221512 Vivix-S FW (Model: FXRD-2530FAW, FXRD-3643FAW, FXRD-4343FAW)

Jul 20, 2022
57 days to decision

K221512 · 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