FDA 510(k) Premarket Notification

# K241125 VIVIX-S 1751S

**CLEARED**

Nov 15, 2024
206 days to decision

K241125 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k241125/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Apr 23, 2024 |
| Decision date | Nov 15, 2024 |
| Days to decision | 206 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Vieworks Co., Ltd.** |
| Location | Gyeonggi-Do, KR |
| Contact | Oh Kevin |
| 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