

**K241113 VIVIX-M**Jan 16, 2025  
269 days to decisionK241113 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k241113/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Apr 22, 2024
Decision date	Jan 16, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>LK Consulting Group USA, Inc.</b>
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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