

**K260820 VIVIX-S 4386W (FXRD-4386WA)**Jun 18, 2026  
97 days to decisionK260820 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k260820/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Mar 13, 2026
Decision date	Jun 18, 2026
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vieworks Co., Ltd.</b>
Location	Gyeonggi-Do, KR
Contact	Juin Lee
510(k) history	21 submissions · 21 cleared · 2007-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260820/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 10, 2026