

**K162518 1012WCC, 1012WGC**Oct 6, 2016  
27 days to decisionK162518 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k162518/>**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	Sep 9, 2016
Decision date	Oct 6, 2016
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rayence Co., Ltd.</b>
Location	Houston, TX, US
Contact	KEVIN KIM
510(k) history	38 submissions · 38 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162518/> 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 May 16, 2026