

**K223930 A1417MCW/A1717MCW/F1417MCW**Mar 6, 2023  
66 days to decisionK223930 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k223930/>**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	Dec 30, 2022
Decision date	Mar 6, 2023
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>H&amp;abyz Co., Ltd.</b>
Location	Yongin-Si, KR
Contact	Jimin Han
510(k) history	4 submissions · 4 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Wise Company, Inc.</b>
Contact	Sanglok Lee

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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