

K213497 ADD (Model Name: HAD1417MCW), ADD (Model Name: HAD1717MCW)Nov 15, 2021
14 days to decisionK213497 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k213497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 1, 2021
Decision date	Nov 15, 2021
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	H&abyz Co., Ltd.
Location	Yongin-Si, KR
Contact	Hyunook (David) Han
510(k) history	4 submissions · 4 cleared · 2021-2025

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