

K203188 ADDMar 12, 2021
136 days to decisionK203188 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k203188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Oct 27, 2020
Decision date	Mar 12, 2021
Days to decision	136 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	Namkyu Hur
510(k) history	4 submissions · 4 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Gms Consulting Co., Ltd.
Contact	Im Do Gyun

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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