

K200018 HAD1717MCJan 31, 2020
28 days to decisionK200018 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k200018/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jan 3, 2020
Decision date	Jan 31, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	H&Abyz
Location	Yongin-Si, KR
Contact	Nam Kyu Hur
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	April Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200018/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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