

K232082 EXPD 4343SFeb 13, 2024
215 days to decisionK232082 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k232082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jul 13, 2023
Decision date	Feb 13, 2024
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DRTECH Corporation
Location	Seongam-Si, KR
Contact	Lee Juhee
510(k) history	25 submissions · 25 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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