

K220073 RMF-2000Jan 26, 2023
381 days to decisionK220073 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k220073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jan 10, 2022
Decision date	Jan 26, 2023
Days to decision	381 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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