

K243420 HESTIAJul 17, 2025
255 days to decisionK243420 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k243420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Nov 4, 2024
Decision date	Jul 17, 2025
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genoray Co., Ltd.
Location	Flintville, TN, US
Contact	Jiyeon Choi
510(k) history	24 submissions · 24 cleared · 2007-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243420/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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