

K253678 MAMMOMAT B.brilliant (11372950)Jun 18, 2026
209 days to decisionK253678 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k253678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Nov 21, 2025
Decision date	Jun 18, 2026
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	Denise Adams
510(k) history	782 submissions · 782 cleared · 1980-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253678/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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