

K193166 MAMMOMAT RevelationJun 12, 2020
210 days to decisionK193166 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k193166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Nov 15, 2019
Decision date	Jun 12, 2020
Days to decision	210 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	Martin Rajchel
510(k) history	779 submissions · 779 cleared · 1980-2026

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