

K210151 Digimamo DMar 1, 2022
404 days to decisionK210151 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k210151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jan 21, 2021
Decision date	Mar 1, 2022
Days to decision	404 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vmi Tecnologias Ltda
Location	Aparecido De Oliveira, Lagoa Santa, BR
Contact	Siele Santos
510(k) history	3 submissions · 3 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Kamm and Associates
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210151/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026