FDA 510(k) Premarket Notification

K210151 Digimamo D

CLEARED

Mar 1, 2022
404 days to decision

K210151 · 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