FDA 510(k) Premarket Notification

K211541 MammoScreen 2.0

CLEARED

Nov 26, 2021
191 days to decision

K211541 · Product code: **QDQ** · Radiology
Source: https://www.510kdatabase.net/k211541/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	May 19, 2021
Decision date	Nov 26, 2021
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Therapixel**
Location	Valbonne, FR
Contact	Quentin De Snoeck
510(k) history	6 submissions · 6 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Domecus Consulting Services, LLC**
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov