FDA 510(k) Premarket Notification

K211720 Planmed Clarity 2D, Planmed Clarify S

CLEARED

Jul 18, 2022
409 days to decision

K211720 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k211720/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jun 4, 2021
Decision date	Jul 18, 2022
Days to decision	409 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Planmed OY**
Location	Helsinki, FI
Contact	Niina Vuorikallas
510(k) history	20 submissions · 20 cleared · 1992-2025