FDA 510(k) Premarket Notification

K192317 Planmed Clarity 2D and Clarity S

CLEARED

Oct 23, 2020
424 days to decision

K192317 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k192317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Aug 26, 2019
Decision date	Oct 23, 2020
Days to decision	424 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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