FDA 510(k) Premarket Notification

K042671 PLANMED SOPHIE NUANCE CLASSIC

CLEARED

Nov 19, 2004
51 days to decision

K042671 · Product code: **IZH** · Radiology
Source: https://www.510kdatabase.net/k042671/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Sep 29, 2004
Decision date	Nov 19, 2004
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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