FDA 510(k) Premarket Notification

K212208 Philips IntelliVue GuardianSoftware (Rev. E.0X)

CLEARED

Sep 30, 2021
77 days to decision

K212208 · Product code: **DXJ** · Cardiovascular
Source: https://www.510kdatabase.net/k212208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Cathode-ray Tube, Medical (DXJ)
Date received	Jul 15, 2021
Decision date	Sep 30, 2021
Days to decision	77 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medizin Systeme Boeblingen GmbH**
Location	B?blingen, DE
Contact	Johannes Schmid
510(k) history	48 submissions · 48 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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