FDA 510(k) Premarket Notification

K212227 Philips MR Patient Care Portal

CLEARED

Sep 30, 2021
76 days to decision

K212227 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k212227/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 16, 2021
Decision date	Sep 30, 2021
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Invivo Corporation**
Location	Pewaukee, WI, US
Contact	Maria Keelan
510(k) history	29 submissions · 29 cleared · 2005-2021