FDA 510(k) Premarket Notification

K211046 eCareManager 4.5

CLEARED

Jun 3, 2022
421 days to decision

K211046 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k211046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Apr 8, 2021
Decision date	Jun 3, 2022
Days to decision	421 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visicu, Inc.**
Location	Lake Forest, CA, US
Contact	Janine Treter
510(k) history	7 submissions · 7 cleared · 2000-2022