FDA 510(k) Premarket Notification

K200856 SmartLinx Vitals Plus Patient Monitoring System

CLEARED

Jul 10, 2020
100 days to decision

K200856 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k200856/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Apr 1, 2020
Decision date	Jul 10, 2020
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Capsule Technologie Sas**
Location	Andover, MA, US
Contact	Peter Kelley
510(k) history	4 submissions · 4 cleared · 2015-2021