FDA 510(k) Premarket Notification

CLEARED

K180734 SmartLinx Vitals Plus Patient Monitoring System

Aug 8, 2018
141 days to decision

K180734 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k180734/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Mar 20, 2018
Decision date	Aug 8, 2018
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Capsule Technologie**
Location	Deer Field, IL, US
Contact	Maylin Truesdell
510(k) history	5 submissions · 5 cleared · 2001-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k180734/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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