

K183638 SmartLinx Vitals Plus Patient Monitoring System

Apr 17, 2019
112 days to decision

K183638 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k183638/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 26, 2018
Decision date	Apr 17, 2019
Days to decision	112 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/k183638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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