

**K200856 SmartLinx Vitals Plus Patient Monitoring System**Jul 10, 2020  
100 days to decisionK200856 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k200856/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200856/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026