

**K221879 Patient Monitor, models LM-8, LM-10, LM-12 and LM-15**Aug 10, 2022  
43 days to decisionK221879 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k221879/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 28, 2022
Decision date	Aug 10, 2022
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Caf Medical Solutions, Inc.</b>
Location	Hockley, TX, US
Contact	Oscar Arriaga Yamin
510(k) history	3 submissions · 3 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Compliance 4 Device</b>
Contact	Juan Tezak

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221879/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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