

**K211046 eCareManager 4.5**Jun 3, 2022  
421 days to decisionK211046 · Product code: **MSX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Apr 8, 2021
Decision date	Jun 3, 2022
Days to decision	421 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Visicu, Inc.</b>
Location	Lake Forest, CA, US
Contact	Janine Treter
510(k) history	7 submissions · 7 cleared · 2000-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211046/> 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 27, 2026