

**K232048 Cogent™ Hemodynamic Monitoring System**Dec 20, 2023  
163 days to decisionK232048 · Product code: **DXG** · CardiovascularSource: <https://www.510kdatabase.net/k232048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Jul 10, 2023
Decision date	Dec 20, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cogent™ HMS

**APPLICANT**

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Company	<b>Icu Medical</b>
Location	Lake Forest, IL, US
Contact	Diane Stockman
510(k) history	5 submissions · 5 cleared · 2017-2023

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232048/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 24, 2026