

**K220527 PADnet Xpress**Oct 20, 2022  
238 days to decisionK220527 · Product code: **JOM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k220527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic (JOM)
Date received	Feb 24, 2022
Decision date	Oct 20, 2022
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Collaborative Care Diagnostics, LLC, D.B.A. Biomedix</b>
Location	Eagan, MN, US
Contact	James Hartnett
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220527/> 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 25, 2026