

**K220328 EasyStat 300**Jul 26, 2024  
903 days to decisionK220328 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k220328/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Feb 4, 2022
Decision date	Jul 26, 2024
Days to decision	903 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medica Corporation</b>
Location	Bedford, MA, US
Contact	Photios Makris
510(k) history	7 submissions · 7 cleared · 2011-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220328/> 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 13, 2026