

**K251281 Nova Max Creat eGFR Monitoring System**Jan 21, 2026  
272 days to decisionK251281 · Product code: **SHB** · Chemistry  
Source: <https://www.510kdatabase.net/k251281/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Creatinine Test System For At Home Prescription Use (SHB)
Date received	Apr 24, 2025
Decision date	Jan 21, 2026
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nova Biomedical Corporation</b>
Location	Waltham, MA, US
Contact	Mariya Cesnulevicius
510(k) history	40 submissions · 40 cleared · 2011-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251281/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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