

**K231192 RIGHTEST Blood Glucose Monitoring System Max Tel**Jan 19, 2024  
267 days to decisionK231192 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k231192/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Apr 27, 2023
Decision date	Jan 19, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bionime Corporation</b>
Location	Great Neck, NY, US
Contact	Yu chi Huang
510(k) history	21 submissions · 21 cleared · 2005-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Dynamic Biotech, Inc. Db. Ivdd Regulatory Consultant</b>
Contact	Feng-Yu Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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