

K240637 RIGHTEST Blood Glucose Monitoring System Max TelNov 4, 2024
243 days to decisionK240637 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k240637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 6, 2024
Decision date	Nov 4, 2024
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bionime Corporation
Location	Great Neck, NY, US
Contact	Kay Wu
510(k) history	21 submissions · 21 cleared · 2005-2024

REGULATORY CONSULTANT

Consulting firm	Dynamic Biotech, Inc. Db. Ivdd Regulatory Consultant
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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