

K053635 MODIFICATION TO RIGHTEST BLOOD GLUCOSE MONITORING SYSTEMFeb 21, 2006
54 days to decisionK053635 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k053635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 29, 2005
Decision date	Feb 21, 2006
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionime Corporation
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	21 submissions · 21 cleared · 2005-2024

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