FDA 510(k) Premarket Notification

K072054 RIGHTEST BLOOD GLUCOSE MONITORING SYSTEM, MODEL GM310

CLEARED

Feb 28, 2008
217 days to decision

K072054 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k072054/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jul 26, 2007
Decision date	Feb 28, 2008
Days to decision	217 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k072054/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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