FDA 510(k) Premarket Notification

K133522 RIGHTEST DIABETES MANAGEMENT SOFTWARE AND ADAPTER (EXISTING CLEARED K113007),RIGHTEST NEW ADAPTERS-3,GE DIABETES MANAGEM

CLEARED

Apr 17, 2014
153 days to decision

K133522 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k133522/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Nov 15, 2013
Decision date	Apr 17, 2014
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bionime Coporation**
Location	Mission Viejo, CA, US
Contact	Feng-Yu Lee
510(k) history	3 submissions · 3 cleared · 2014-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k133522/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026