

K160365 BLE Smart Blood Glucose Monitoring System, BLE Smart Professional Blood Glucose Monitoring System

Sep 28, 2016
232 days to decision

K160365 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k160365/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Feb 9, 2016
Decision date	Sep 28, 2016
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infopia Co, Ltd.
Location	Anyang Kvunggi, KR
Contact	NA YUN KIM
510(k) history	20 submissions · 20 cleared · 2005-2016

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k160365/> 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 2, 2026