

K133045 ELEMENT TM LITE BLOOD GLUCOSE MONITORING SYSTEMApr 10, 2014
195 days to decisionK133045 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k133045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Sep 27, 2013
Decision date	Apr 10, 2014
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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