

K103021 ELEMENT PLUS BLOOD GLUCOSE MONITORING SYSTEMNov 4, 2011
388 days to decisionK103021 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k103021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Oct 12, 2010
Decision date	Nov 4, 2011
Days to decision	388 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infopia Co, Ltd.
Location	Anyang Kvanggi, KR
Contact	Priscilla Chung
510(k) history	20 submissions · 20 cleared · 2005-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103021/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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