

K132633 OKMETER DIRECT BLOOD GLUCOSE MONITORING SYSTEMAug 14, 2014
357 days to decisionK132633 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k132633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Aug 22, 2013
Decision date	Aug 14, 2014
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ok Biotech Co., Ltd.
Location	Hsin-Chu City, TW
Contact	JEN KE-MIN
510(k) history	9 submissions · 9 cleared · 2007-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132633/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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