October 7, 2022

OK BioTech Co., Ltd.
Laurie Liu
Special Assistant to GM
No. 91, Sec. 2, Gongdao 5th Rd.
Hsinchu City, 30070, Taiwan

Re: K213061
Trade/Device Name: SuperCheck Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: July 6, 2022
Received: July 8, 2022

Dear Laurie Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213061

Device Name
SuperCheck Pro Blood Glucose Monitoring System

Indications for Use *(Describe)*
The SuperCheck Pro Blood Glucose Monitoring System is comprised of the SuperCheck Pro Blood Glucose Meter and SuperCheck Pro Blood Glucose Test Strips.
The SuperCheck Pro Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger, forearm, upper arm, calf, thigh, or palm. It is intended to be used by a single person and should not be shared. The SuperCheck Pro Blood Glucose Monitoring System is for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.
The SuperCheck Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use with neonates.
Alternative site testing should be done only during steady-state conditions (when blood glucose is not changing rapidly).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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訊映光電股份有限公司

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TEL：886-3-5160258
FAX：886-3-5160028

510(k) Summary

Submission Number: K213061

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Submitter Information

Company Name	OK Biotech Co., Ltd.
Address	No. 91, Sec. 2, Gongdao 5th Rd., Hsinchu City 30070, Taiwan.
Telephone	+886-3-516-0258
Fax	+886-3-516-0028
Date of Submission	October 7, 2021
Contact Person	Laurie Liu
Title	Special assistant to GM
E-mail	Laurie.liu@okmeter.com

II. Regulatory information:

Proprietary Name	SuperCheck Pro Blood Glucose Monitoring System
Model No.	Meter: OK-2MJB, Strips: OK2M
Common Name	Blood Glucose Monitoring System
Regulation section	21 CFR § 862.1345, Glucose Test System
Regulatory Class	Class II
Product Code	NBW, Blood glucose test system, over the counter
Classification Panel	Clinical Chemistry

III. Predicate Device Information

Manufacturer	Biotest Medical Corp.
Device Name	WowGoHealth Blood Glucose Monitoring System
510(k) Number	k171785

IV. Indications for Use

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The SuperCheck Pro Blood Glucose Monitoring System is comprised of the SuperCheck Pro Blood Glucose Meter and SuperCheck Pro Blood Glucose Test Strips.

The SuperCheck Pro Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger, forearm, upper arm, calf, thigh, or palm. It is intended to be used by a single person and should not be shared. The SuperCheck Pro Blood Glucose Monitoring System is for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.

The SuperCheck Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use with neonates.

Alternative site testing should be done only during steady-state conditions (when blood glucose is not changing rapidly).

V. Device Description

SuperCheck Pro Blood Glucose Monitoring System is used for determining the approximate concentration of glucose in the blood. A complete kit (starter kit) of SuperCheck Pro Blood Glucose Monitoring System consists of:

1. SuperCheck Pro Blood Glucose Meter
2. SuperCheck Pro Blood Glucose Test Strips
3. OKmeter Control Solution (Level I, II)

Before use, The SuperCheck Pro Blood Glucose Test Strips should be inserted into the SuperCheck Pro Blood Glucose Meter first. Prick a fingertip with a sterile Lancet that installed in the Lancing device and apply the blood drop to the front edge of the Test Strip. Wait for 5 seconds and the Meter will display the test result.

OKmeter Control Solution containing a known amount of glucose that is used to confirm SuperCheck Pro Blood Glucose Meter and SuperCheck Pro Blood Glucose Test Strips are working properly together. Follow the same steps as above but replace the blood drop by OKmeter Control Solution.

OKmeter Control Solution and SuperCheck Pro Blood Glucose Test Strips could be separately bought.

VI. Test Principle:

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The SuperCheck Pro Blood Glucose Monitoring System (Model OK-2MJB) measures the amounts of glucose in whole blood quantitative using fresh capillary whole blood from the fingertip and alternative sites including palm, forearm, upper arm, calf, and thigh. Amperometric technology is used for the detection of glucose from the strip with whole blood sample on the meter. Reagent consisting of glucose dehydrogenase with its cofactor flavin adenine dinucleotide (GDH-FAD) and mediator is deposited onto the reaction area of the test strip with carbon printed electrodes. The testing is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with the enzyme, GDH-FAD, on the test strip. The meter measures the strength of the current which is proportional to the amounts of glucose in the sample and displays the corresponding blood glucose concentration.

VII. Comparison of Technological Characteristics with the Predicate Device

SuperCheck Pro Blood Glucose Monitoring System shares either same or similar intended use, design, performance, and functions of the predicate devices and is therefore substantially equivalent to the predicated device.

Comparison Items	**New device**	**Predicate device (k171785)**
Name of manufacturer	OK Biotech Co., Ltd.	Biotest Medical Corp.
Proprietary Name	SuperCheck Pro Blood Glucose Monitoring System	WowGoHealth Blood Glucose Monitoring System
Model No.	OK-2MJB	GSH-BGM902
Product Code	NBW	NBW
Type of use	Over-the-Counter	Over-the-Counter
Similarities		
Intended Use	The SuperCheck Pro Blood Glucose Monitoring System is comprised of the SuperCheck Pro Blood Glucose Meter and SuperCheck Pro Blood Glucose Test Strips. The SuperCheck Pro Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger, forearm, upper arm, calf,	The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended to be used by a single person and should not be shared. The WowGoHealth Blood Glucose Monitoring System

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Comparison Items	New device	Predicate device (k171785)
	thigh, or palm. It is intended to be used by a single person and should not be shared. The SuperCheck Pro Blood Glucose Monitoring System is for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. The SuperCheck Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use with neonates. Alternative site testing should be done only during steady-state conditions (when blood glucose is not changing rapidly).	(Model GSH-BGM902) is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly). .
Specimen Type	Capillary whole blood	Capillary whole blood
Detecting Range	20~600 mg/dL (1.1~33.3 mmol/L)	20~600 mg/dL (1.1~33.3 mmol/L)
Response Time	5 seconds	5 seconds
Power Requirements	Two 1.5V AAA alkaline batteries	Two 1.5V AAA alkaline batteries
Dimensions	100 mm (L) x 50 mm (W) x 20 mm (H) Approximate 69 g	100 mm (L) x 50 mm (W) x 20 mm (H) Approximate 69 g
Voice Function	No	No
Average calculation (specify)	7, 14, 28, 60 and 90 days	7, 14, 28, 60 and 90 days
Insufficient Blood Warning	Yes	Yes
Eject Button	Yes	Yes

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Comparison Items	New device	Predicate device (k171785)
Enzyme	Flavin adenine dinucleotide-glucose dehydrogenase (FAD-GDH)	Flavin adenine dinucleotide-glucose dehydrogenase (FAD-GDH)
HCT Range	20-60%	20-60%
PC Link	No	No
Downloadable	Bluetooth	Bluetooth
Bluetooth data transmission APP	WOWGOHEALTH APP	WOWGOHEALTH APP
Coding	No	No
Differences		
Test Strips	SuperCheck Pro Blood Glucose Test Strips	WowGoHealth Blood Glucose Test Strip
Sample Volume	0.5μL	1.1μL
Alternate-Site Testing (AST)	palm, forearm, upper arm, calf, and thigh.	Forearm
Control Solution	OKmeter Control Solution	WowGoHealth Control Solution
Operating Condition	50~104°F (10~40°C), 10~85% RH Altitude ≦ 11,161 ft (3,402 m) above the sea level	50~104°F (10~40°C), 20~80% RH Altitude ≦10,744 ft (3,275 m) above the sea level
Strips Storage Conditions	39~104°F(4~40°C)/ 10~85% R.H. (strip included)	35.6~86°F (2~30°C) / 20~80% R.H. (strip included)
Control Solution Storage Conditions	39~ 86°F (4~30°C) (control solution included)	35.6~86 (2~30°C) (control solution included)
Memory Storage	1000 measurements with day and time	500 measurements with day and time
Expiration for strip	Storage：30 months In-Use：180 days	Storage：5 months In-Use：3 months
Expiration for control solution	Storage: 18 months In-Use: 90 days	Storage: 24 months In-Use: 3 months

VIII. Summary of Testing

Non-clinical and clinical studies were conducted to test, verify, and validate the performance of the proposed device according to FDA Guidance issued on September 29, 2020: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use and other relevant standards. Results from these studies show that all performance criteria were met.

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Non-Clinical Testing Summary: Design verification and validation testing was performed to ensure that the SuperCheck Pro Blood Glucose Monitoring System (Model OK-2MJB) met design specifications and requirements. Testing activities included electrical/mechanical safety tests, functional performance tests (precision, linearity, interference, flex studies) as well as disinfection, cleaning, and robustness studies. Software validation was performed for this moderate level of concern device per FDA Guidance Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Testing Summary: A user evaluation confirmed the system accuracy, operation according to design, and ease of use to support the intended use as described in the proposed labeling.

IX. Conclusion

Based on the information provided in this submission, it was concluded that the SuperCheck Pro Blood Glucose Monitoring System (Model OK-2MJB) is substantially equivalent to the predicate device.