August 21, 2018

Applied Biomedical LLC
% Jigar Shah
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, NY 11021

Re: K173658
Trade/Device Name: Confidence Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: July 19, 2018
Received: July 20, 2018

Dear Jigar Shah:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173658

Device Name
Confidence Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Confidence Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The Confidence Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Confidence Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The Confidence Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. The Confidence Blood Glucose Test Strips are for use with the Confidence Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip.

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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510(K) SUMMARY

The assigned 510(K) Number: K 173658

1. Submitter's Identification:

APPLIED BIOMEDICAL LLC

1981 E Miraloma Ave, Unit B

Placentia, CA 92870

TEL: 714 646 3233

FAX: 714 646 3238

Date Summary Revised: August 16, 2018

Official Correspondent's name: Dr. Zakir Murtaza Ph.D.

2. Name of the Device:

Confidence™ Blood Glucose Monitoring System

3. Common or Usual Name:

Glucose Test System, Over-the-Counter

4. Predicate Device Information:

K150214, OneTouch Verio Flex Blood Glucose Monitoring System

5. Classification:

Confidence™ Blood Glucose Meter and Confidence™ Test Strips are Class II devices (US 21 CFR § 862.1345), Product Code NBW.

6. Device Description:

The Confidence™ BGMS consists of test strips stored in a vial with desiccant lining, a hand held blood glucose meter and a control solution. To perform blood glucose test a test strip is removed from the vial and inserted into Confidence™ meter. On inserting the strip meter gets activated and displays a code, user must select a code corresponding to their strip vial using meter's interface, after selecting correct code, meter will be ready to apply sample by showing a droplet on the LCD display. On applying blood on the end of the test strip a countdown starts and meter LCD displays the plasma equivalent value in the blood sample within 10 seconds in mg/dL unit. The user can validate the operation of the system by using provided known algorithm, where generated current is directly proportional to glucose concentration.

7. Intended Use:

The Confidence™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip.

The Confidence™Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Confidence™ Blood Glucose Monitoring is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The Confidence™Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. The Confidence™ Blood Glucose Test for use with the Confidence™ Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples freshly drawn from the fingertip.

8. Comparison to Predicate Devices:

a. Predicate Device:
OneTouch Verio Flex Blood Glucose Monitoring System,

b. Predicate Device 510K number and date of cleared
K150214 (July 31 2015)

c. Predicate Device Comparison Table

Item	Candidate Device Confidence™ Blood Glucose Monitoring System	OneTouch Verio Flex Blood Glucose Monitoring System
Similarities		
510K Issued on	Current Submission	**July 31, 2015**
510 (k) number	K173658	K150214
Intended/Indications for Use	Same	For self-testing outside the body (In vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Not to be used for diagnosis or screening diabetes or for neonatal use
Calibration	Same	Plasma Equivalent
Measurement technology	Same	Amperometry
Sample type	Same	Capillary whole blood
Sample sites	Same	Finger Tip
Enzyme	Same	GDH-FAD
Maximum Altitude	Same	Up to 10,000 feet
Buttons	Same	3 button user input
Weight	Same	Approximately 1.7 ounces
Auditory Indicator	Same	Yes

Differences

Operating Temperature	41-104 ^{o}F (5-40 ^{o}C)	43°F - 111°F (6°C - 44°C)
Operating humidity	10%-85%	10% - 90%
Test range	50-600 mg/dL	20-600 mg/dL
Sample volume	1.2 µL	0.4 µL
Hematocrit	30 – 55 %	20%-60%
Sample Test Time	10 seconds	5 seconds
Calibration Coding	Manual code input	Non-coding
Memory capacity	1500 with date & time (14 & 30 days average)	Non (data transfer to remote station)
Size (L x W x H)	0.88 x 2.28 x 3.15 inches	0.63 x 2.05 x 3.39 inches
Power Source	One 3 Volts, 0.2A (CR2032) battery	Two 1.5 V (AAA) battery
Microprocessor	16 Bit with 16K memory	Multichip Module
Display	Segmented monochrome liquid crystal display	Dot matrix thin film transistor color display
Compatible off-meter software accessories	PrimosApp	One Touch Diabetes Management Software
Alert Alarm	Option to set alerts for testing time	No Alarm
Remote data storage	No	Yes
Controls solution(s)	Single Control (either Low, Medium or High)	Two Controls (Medium and High)
Target Range Indicator	No	Yes
Data Download	Yes, USB only	Yes (via USB or Blue tooth)
Test Strip	Plastic molded strip made of palladium plated solid copper electrodes covered by insert & over molding with plastic	Metal foil electrodes trapped between layers of plastic

Candidate device is similar or very close to the predicate device in its all major claims.

The following are main differences between predicate and candidate device.

I. The strip of candidate device has palladium plated solid copper electrodes which are covered by insert and over molding of plastic, whereas the predicate device has metal foil electrodes trapped between plastic layers.

II. In the candidate device data can be transfer using a cable whereas predicate device transfer data wirelessly.

III. The candidate device has monochrome display with coding whereas predicate has color display with no coding.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The new Applied Biomedical LLC Confidence, a blood glucose monitoring device was verified against users need and intended uses as to fulfill through Design Input requirements.

The subject device demonstrated substantial equivalent performance to the predicate device and YSI. The following standards were used for non-clinical test:

i) EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005).
ii) EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).
iii) ISO 14971 - Medical devices —Application of risk management to medical devices (2007).
iv) IEC/EN 60601-1-2 (EMC Testing)
v) IEC 61010-1-04 - Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements.
vi) IEC 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements.
vii) IEC 61010-2-101:04-Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory use - Part 2-101: Particular Requirements for In-Vitro Diagnostic (IVD) Medical Equipment

10. Discussion of Clinical Tests Performed:

A system accuracy evaluation was performed by comparing glucose value obtained by trained person using Confidence™ BGMS from finger stick blood of the 265 subjects with the scaled glucose value obtained by FDA cleared reference method (YSI 2300). The study was performed at two sites using three strip lots and eleven meters. The results demonstrated that Confidence™ BGMS is substantially equivalent in its performance with YSI.

System Accuracy Results Relative to YSI Values
(Glucose Concentrations Range 60-500 mg/dL)

Percent (and Number) of meter results that match the YSI reference (N=270)		
Within ± 10 mg/dL or ±10%	**Within ± 10 mg/dL or ±15%**	**Within ±10 mg/dL or ± 20 %**
74.8% (202/270)	99.6% (269/270)	00% (270/270)

The Confidence™ BGMS liner regression data relative to YSI reference value was compared with liner regression data of Touch® VerioFlex™ BGMS (Predicate Device) relative to YSI reference value in following table. All values

are showing excellent linearity, the slope and R^2 are comparable to predicate device, indicating that the Confidence™ BGMS is substantially equivalent to the VerioFlex™ BGMS as per predicate device labeling.

Liner Regression data for Accuracy of Confidence™ BGMS and Predicate Device Relative to YSI Values

BGMS	Participants	Slope	Intercept	R^2
Touch® VerioFlex™	300*	0.99	2.61	0.99
Confidence™	270	0.99	3.83	0.99

*From Product labeling

A user study was performed to demonstrate that lay users could use the Confidence Glucose Monitoring Systems and obtain accurate results. The study was performed by 181 users; they never have used the candidate device before. The results obtained by using candidate device were compared with the scaled glucose values obtained by YSI. The results demonstrated the Confidence™ BGMS is substantially equivalent in lay users' hand to its performance with YSI.

Users Performance Results Relative to YSI Values
(Glucose Concentrations Range 60-480 mg/dL)

Percent (and number) of meter results that match YSI reference (N=187)	
Within ±10 mg/dL or ± 10 %	**Within ±15 mg/dL or ± 15 %**
90.4% (169/187	100% (187/187)

The linear regression data obtained by user with the Confidence™ BGMS relative to YSI reference value was compared with liner regression data of values obtained by user using Touch® VerioFlex™ BGMS (Predicate Device) relative to YSI are showed in following table. All values are showing excellent linearity, the slope and R^2 are comparable with predicate device, indicating that the Confidence™ BGMS is substantially equivalent to the VerioFlex™ BGMS as per predicate device labeling.

Liner Regression data of Confidence™ BGMS and Predicate Device Relative to YSI

BGMS	Participants	Slope	Intercept	R^2
Touch® VerioFlex™	172*	0.99	2.98	0.98
Confidence™	187	1.01	0.29	0.99

*From Product's labeling

A survey was also conducted using 181 lay users about the instruction to use and steps to perform the test, cleaning and error codes description. The participants had no difficulty to perform the test and understood the instructions about cleaning and error codes.

11. Conclusions:

The Confidence™ Glucose Monitoring Systems is substantially equivalent in its intended use, performance, safety, effectiveness and underlying scientific and operating principal used, to the predicate device, OneTouch Verio Flex Blood Glucose Monitoring System.