February 14, 2020

LifeScan Europe GmbH
Niki Skelly
Regulatory Affairs Consultant
LifeScan Scotland Ltd.
Beechwood Park North, Inverness, GB iv1 3ed Scotland

Re: K193475
Trade/Device Name: OneTouch Verio Reflect Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: December 13, 2019
Received: December 16, 2019

Dear Niki Skelly:

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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k193475

Device Name
OneTouch Verio Reflect Blood Glucose Monitoring System

Indications for Use *(Describe)*
The OneTouch Verio Reflect Blood Glucose Monitoring System is composed of the OneTouch Verio Reflect Meter and OneTouch Verio Test Strips. The OneTouch Verio Reflect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The OneTouch Verio Reflect Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

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.

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510(k) Summary

(as required by section 807.92(c))

The assigned 510(k) number is K193475

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Date Prepared	December 3rd, 2019
Device Trade Name	OneTouch Verio Reflect Blood Glucose Monitoring System
Common Name	Glucose Test System
Classification	OneTouch Verio Reflect Blood Glucose Meters and OneTouch Verio Test Strips are Class II devices (21 CFR § 862.1345), Product Code NBW
System Description	The OneTouch Verio Reflect Blood Glucose Monitoring System consists of the OneTouch Verio Reflect Blood Glucose Meter, OneTouch Verio Test Strips, OneTouch Verio Level 3 and Level 4 Control Solutions, Lancing Device and Sterile Lancets. The OneTouch Verio Reflect Blood Glucose Monitoring System measures the glucose content of a blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement. The OneTouch Verio Reflect meter also contains tools to aid diabetes management which include a dynamic range indicator, test tracker, blood sugar mentor, trend90 average blood glucose and meal and advanced tagging.
Predicate Device	OneTouch Verio Flex Blood Glucose Monitoring System (K150214, Cleared 31st July 2015)
Intended Use/Indications for Use	The OneTouch Verio Reflect Blood Glucose Monitoring System is composed of the OneTouch Verio Reflect Meter and OneTouch Verio Test Strips. The OneTouch Verio Reflect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh

	capillary whole blood samples drawn from the fingertips. The OneTouch Verio Reflect Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

Comparison to Predicate Device	The Subject device is different from the predicate device in the following aspects:
	• Meter:
	  • Blood Glucose Algorithm: A modified blood glucose calculation, reduces sensitivity to interferences and includes additional error trap failsafe mode for sample mis-application.
	  • Software/Firmware changes: Dynamic Color Range Indicator, Blood Sugar Mentor for motivational messages, Test tracker, Meal and Advanced tagging (Carbs, Stress, Illness, Meds, Exercise), Results summary charts, Averages (Before and After Meal), Trend 90 feature for 90 day blood glucose average.
	• Ergonomic/physical Design: Changes to size, shape
	• Electronic/hardware: use of 2x coin cell battery instead of 1, separation of Multichip module constituent parts, TFT (Thin Film Transistor) Color LCD display and addition of backlight on the meter display

	• Labelling: • New branding and Instructions for Use There are no changes to the OneTouch Verio Test Strips or the OneTouch Verio Level 3 and Level 4 Control Solutions cleared for use with the predicate OneTouch Verio Flex Blood Glucose Monitoring System 510(k) (K150214). There have been no changes to the intended use, operating principle or scientific technology.

Technological Characteristics

Specifications and Features	**OneTouch Verio Flex Blood Glucose Monitoring System (Predicate Device)**	**OneTouchVerio Reflect Blood Glucose Monitoring System (Subject Device)**
Scientific Technology	Amperometric detection	Same
Operating Principle	Electrochemical reaction with GDH-FAD Glucose Dehydrogenase	Same
Calibration	Plasma-equivalent	Same
Sample Site	Fingertip only	Same
Sample Type	Capillary	Same
Sample Volume	Minimum 0.4ul	Same
Test Time	5 seconds	Same
Glucose Measurement	20 - 600 mg/dL (1.1 - 33.3	Same

Specifications and Features	OneTouch Verio Flex Blood Glucose Monitoring System (Predicate Device)	OneTouchVerio Reflect Blood Glucose Monitoring System (Subject Device)
Range	mmol/L)	
Hematocrit Range	20-60%	Same
Operating Temperature Range	10°C – 40°C (50°F – 104°F)	6°C – 44°C (43°F – 111°F)
Operating Relative Humidity Range	10 % - 90%, non-condensing	Same
Test Strip Storage (Unopened Vial)	22 months 5°C – 30°C (41°F – 86°F) up to 65% RH	22 months 5°C – 30°C (41°F – 86°F) 10-90% RH
Test Strip Storage (Opened Vial)	6 months from first opening	Same
Control Solution Ranges	Level 3 : target glucose concentration 120 mg/dL; Range 102 - 138 mg/dL (5.7 - 7.7 mmol/L) Level 4 : target glucose concentration 350 mg/dL; Range 298 - 403 mg/dL (16.5 - 22.4 mmol/L)	Same
Coding	No calibration code is required	Same
Data Download	Via USB or Bluetooth	Same

Specifications and Features	OneTouch Verio Flex Blood Glucose Monitoring System (Predicate Device)	OneTouchVerio Reflect Blood Glucose Monitoring System (Subject Device)
	Low Energy	
Compatible off-meter software accessories	OneTouch Reveal	Same
Power source	1 x 3V CR2032	2 x 3V CR2032
Meter Size (L x W x H)	Approx 3.39 x 2.05 x 0.63 inches	Approx 3.97 x 1.69 x 0.61 inches
Weight	Approx 1.7 ounces	Approx 1.9 ounces
User Interface Screen	No Menu or text Graphics to instruct user to apply sample to strip	Menu driven with text and icon based information.

Summary of Performance Characteristics

The OneTouch Verio Reflect Blood Glucose Monitoring System (meter, strips, and control solutions) was designed and tested in accordance with FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (October 2016) and EN ISO 15197:2015. Analytical performance testing included, repeatability, intermediate precision hematocrit, short sample volume, perturbation, interference and linearity testing. A user performance evaluation was also conducted in accordance with FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (October 2016; Section VI.C) which assessed accuracy of results and usability of the device in the hands of

intended users. The OneTouch Verio Reflect Blood Glucose Monitoring System performed similarly to both the predicate device as well as to a laboratory reference method, the Yellow Springs Instrument (YSI 2300 STAT PLUS glucose analyzer).

Lay User Method Comparison Study

A Lay User Method Comparison study of the OneTouch Verio Reflect Blood Glucose Monitoring System (BGMS) was conducted in accordance with FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (October 2016; Section VI.C*)* to validate the accuracy performance of the System in the hands of the user. A comparison of the Lay User OneTouch Verio Reflect Blood Glucose Monitoring System fingertip results compared to glucose results obtained on the recognized glucose reference method (YSI 2300 STAT PLUS glucose analyzer) are summarized below. Glucose values from fingertip capillary blood samples obtained from 354 lay persons showed the following results:

Verio Reflect User Evaluation Performance – Summary of data within specified mg/dL of the YSI 2300 reference instrument for glucose concentrations across the entire range:

Dataset	Within ±5% n (%)	Within ±10% n (%)	Within ±15% n (%)	Within ±20% n (%)
Subject self-test	222/354 (62.7)	333/354 (94.1)	351/354 (99.2)	354/354 (100)

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence

Design verification and validation testing confirmed that the performance, safety, and effectiveness of the OneTouch Verio Reflect Blood Glucose Monitoring System were met against all design input specifications and the system can be considered substantially equivalent to that of the predicate device. Evaluations included repeatability, intermediate precision and linearity. The OneTouch Verio Reflect Meter also meets the requirements of FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (October 2016), EN ISO 15197:2015 and applicable recognized electrical and safety standards including FCC requirements.

Conclusions

The OneTouch Verio Reflect Blood Glucose Monitoring System is substantially equivalent in its intended use, performance, safety, effectiveness and underlying scientific and operating principles to the predicate, the OneTouch Verio Flex Blood Glucose Monitoring System (K150214).