DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 31, 2015

LIFESCAN EUROPE
ALISON WILSON
REGULATORY AFFAIRS PROJECT MANAGER
BEECHWOOD PARK NORTH
INVERNESS IV2 3ED, GREAT BRITAIN

Re: K150214
Trade/Device Name: One Touch Verio Flex™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: June 25, 2015
Received: July 02, 2015

Dear Alison Wilson:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150214

Device Name
OneTouch Verio Flex™ Blood Glucose Monitoring System

Indications for Use *(Describe)*
The OneTouch Verio Flex™ 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 fingertip. The OneTouch Verio Flex™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be be shared.
OneTouch Verio Flex™ 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 OneTouch Verio Flex™ Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes, or for neonatal use.
The OneTouch® Verio Test Strips are for use with the OneTouch Verio Flex™ Blood Glucose Meter to quantitatively measure glucose drawn from the fingertips.

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))

Sponsor	LifeScan Europe, a Division of Cilag GmbH International Gubelstrasse 34 Zug, Switzerland 6300
Correspondent	Alison Wilson, Regulatory Affairs Project Manager LifeScan Scotland Ltd. Beechwood Park North Inverness, IV2 3ED United Kingdom Phone: +44(0) 1463 721256 e-mail: awilson4@its.jnj.com Alternate 510(k) Contact: Oyinkan Donaldson, Senior Regulatory Affairs Manager LifeScan Scotland Ltd Beechwood Park North Inverness, IV2 3ED United Kingdom Phone: +44 01463 721259 Mobile: +44 (0) 7909935151 Fax: +44 (0)1463 722000 e-mail: odonalds@its.jnj.com
Date Prepared	May 2015
Device Trade Name	OneTouch Verio Flex Blood Glucose Monitoring System
Common Name	Glucose Test System

Classification	OneTouch Verio Flex™ Blood Glucose Meters and OneTouch Verio™ Test Strips are Class II devices (21 CFR § 862.1345), Product Code NBW, LFR OneTouch Verio ™ Control Solutions are Class I devices (21 CFR §862.1660), Product Code JJX Lancing Device and Sterile Lancets are Class I (exempt) devices (21 CFR § 878.4800), Product Code FMK
System Description	The OneTouch Verio Flex Blood Glucose Monitoring System consists of the OneTouch Verio Flex Blood Glucose Meter, OneTouch® Verio® Test Strips, OneTouch® Verio® Level 3 and Level 4 Control Solutions, Lancing Device and Sterile Lancets. The OneTouch Verio Flex 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.
Predicate Device	OneTouch® Verio™ Blood Glucose Monitoring System (K131363, Cleared 30th August 2013)
Intended Use/Indications for Use	The OneTouch Verio Flex 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 fingertip. The OneTouch Verio Flex _Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. OneTouch Verio Flex 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 OneTouch Verio Flex Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes, or

	for neonatal use. The OneTouch® Verio™ Test Strips are for use with the OneTouch Verio Flex Blood Glucose Meter to quantitatively measure glucose drawn from the fingertips.
Comparison to Predicate Device	The Subject device is different from the predicate device in the following aspects: • Meter: o Ergonomic/physical design: Changes to size, shape and color o Electronic/hardware: Strip port connector o Software/Firmware changes: Modified Blood Glucose Algorithm and addition of a range indicator software feature. • Labelling: o New branding and Instructions for Use There are no changes to the OneTouch® Verio® Test Strips or the OneTouch® Verio® Level 3 (Mid) and Level 4 (High) Control Solutions cleared for use with the predicate OneTouch® Verio™ Blood Glucose Monitoring System 510(k) (K131363). There have been no changes to the intended use, operating principle or scientific technology.
Technological Characteristics	There has been no change to the fundamental scientific technology, which is amperometric detection. The operating principle remains electrochemical reaction.
Summary of Performance Characteristics	The OneTouch Verio Flex Blood Glucose Monitoring System (meter, strips, and control solutions) was designed and tested in accordance with ISO 15197:2013(E). Analytical performance testing included system

	accuracy, repeatability, intermediate precision and linearity testing. A user performance evaluation assessed accuracy of results and usability of the device in the hands of intended users. The OneTouch Verio Flex Blood Glucose Monitoring System performed similarly to both the predicate device as well as to a laboratory reference method, the Yellow Springs Instrument (YSI).

Method Comparison Performance

A study evaluating the glucose values from the OneTouch Verio Flex Blood Glucose monitoring System (obtained by healthcare professional fingersick samples from diabetic subjects) and compared to the glucose results obtained by the recognized glucose reference method (YSI 2300) from 115 subjects showed the following results:

NOTE: first test sample data is presented here.

Method Comparison Results for Glucose Concentrations <75 mg/dL

Percent (and number) of meter results that match the YSI reference

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
77.8% (42/54)	100% (54/54)	100% (54/54)

Method Comparison Results for Glucose Concentrations ≥75 mg/dL

Percent (and number) of meter results that match the YSI reference

Within ±5%	Within ±10%	Within ±15%	Within ±20%
62.9% (183/291)	94.8% (276/291)	98.6% (287/291)	99.3% (289/291)

System Accuracy Results for Glucose concentrations across the glucose range:
Percent (and number) of meter results that match the YSI reference

Within ±10 mg/dL (±0.83 mmol/L) or ±15%	Within ±10 mg/dL (±0.83 mmol/L) or ±20%
98.8% (341/345)	99.4% (343/345)

A linear regression ananlysis of the method comparison study data demonstrated that the OneTouch®VerioFlex™ Blood Glucose Monitoring System (subject device) and the OneTouch® Verio™ Blood Glucose Monitoring System (predicate device) are substantially equivalent; and that the subject device compared well to the laboratory reference instrument (YSI analyzer).

NOTE: first test sample data is presented here and within the product labelling

Regression Statistics for the Subject and Predicate Device compared to YSI

BGMS	Lot #	# Partici-pants	# Tests	Slope [95% CI]	Intercept [95% CI] (mg/dL)	Std. Error ($S_{y.x}$) (mg/dL)	R^2
OneTouch® Verio™	D	115	115	0.97 [0.95 to 0.99]	6.05 [2.41 to 9.69]	10.15	0.99
OneTouch®VerioFlex™	A	115	115	1.00 [0.98 to 1.02]	-0.31 [-4.04 to 3.42]	10.41	0.99
	B	115	115	0.99 [0.97 to 1.01]	1.14 [-2.91 to 5.20]	11.33	0.99
	C	115	115	1.01 [0.99 to 1.03]	0.01 [-4.13 to 4.16]	11.57	0.99
	3 lots	345	345	1.00 [0.99 to 1.01]	0.28 [-2.00 to 2.56]	11.11	0.99

Table above reflects regression limits of 15mg/dL <75mg/dl and % results within 15%>75mg/dL

Lay User Performance Evaluation

A study to validate the accuracy performance of the OneTouch Verio Flex Blood Glucose Monitoring System in the hands of the user was undertaken. A comparison of the Lay User OneTouch Verio Flex 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 by 172 lay persons showed the following results:

Subject Fingertip Results for Glucose Concentrations <75 mg/dL

Percent (and number) of meter results that match the YSI reference

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
76.2% (16/21)	95.2% (20/21)	95.2% (20/21)

Subject Fingertip Results for Glucose Concentrations ≥75 mg/dL

Percent (and number) of meter results that match the YSI reference

Within ±5%	Within ±10%	Within ±15%	Within ±20%
58.3% (88/151)	88.7% (134/151)	98.0% (148/151)	99.3% (150/151)

Precision (Repeatability)

Within Run Precision (300 Venous Blood Samples Tested per glucose level)

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
20	18.3	0.63	3.43
40	36.5	0.83	2.26
90	88.5	1.72	1.95
130	127.9	2.50	1.95
200	199.3	3.94	1.98
350	344.6	6.18	1.79
600	583.4	10.54	1.81

Results show that the greatest variability observed between test strips when tested with blood is 1.72mg/dl SD or less at glucose levels less than 100mg/dl, or 1.98% or less at glucose levels at 100mg/dl or above

Total Precision (Intermediate Precision)

(600 Control Solution Tests)

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Very Low (0-24)	12.46	**0.57**	4.54
Low (25 – 49)	37.14	**0.92**	2.48
Mid (102 – 138)	117.68	2.41	**2.05**
High (298 – 403)	348.99	8.31	**2.38**
Very High (446-604)	515.18	13.53	**2.63**

System Accuracy performance in accordance with ISO 15197:2013(E)

Accuracy of the subject device was analysed and assessed in compliance with the product design requirements in accordance with the requirements of ISO 15197:2013(E) Clause 6.3 System Accuracy and Clause 8 User Performance Evaluation.

System Accuracy in compliance with ISO 15197:2013(E) Clause 6.3:

A study was conducted to evaluate glucose values from fingertip capillary blood samples obtained by healthcare professionals from 100 subjects in accordance with the glucose ranges required by ISO15197:2013 Clause 6.3.5. The analysis showed the following results:
100% for all 3 test strip lots within ±15mg/dl of the medical laboratory values at glucose concentrations below 100mg/dL and 99.3%, 100%, 98.7% within ±15% of the medical laboratory values at glucose concentrations at or above 100mg/dL.

System Accuracy Results for Glucose Concentrations <100 mg/dL

Percent (and number) of meter results that match the YSI reference

Test Strip Lot Number	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
A	86% (43/50)	98% (49/50)	100% (50/50)
B	80% (40/50)	98% (49/50)	100% (50/50)
C	80% (40/50)	98% (49/50)	100% (50/50)
Pooled Results for Lots A-C	82.0% (123/150)	98.0% (147/150)	100% (150/150)

System Accuracy Results for Glucose Concentrations ≥100 mg/dL

Percent (and number) of meter results that match the YSI reference

Test Strip Lot Number	Within ±5%	Within ±10%	Within ±15%
A	65.3% (98/150)	93.3% (140/150)	99.3% (149/150)
B	64.0% (96/150)	96.0% (144/150)	100% (150/150)
C	59.3% (89/150)	94.7% (142/150)	98.7% (148/150)
Pooled Results for Lots A-C	62.9% (283/450)	94.7% (426/450)	99.3% (447/450)

System accuracy results across the glucose range tested: concentrations between 38.2 mg/dL and 466.3 mg/dL

Percent (and number) of meter results that match the YSI reference

Test Strip Lot Number	Within ±15mg/dL or ±15%
A	99.5% (199/200)
B	100% (200/200)
C	99.0% (198/200)
Pooled Results for A-C	99.5% (597/600)

NOTE: Where 38.2 mg/dL represents the lowest glucose reference value and 466.3 mg/dL represents the highest glucose reference value (YSI value).

User Performance Evaluation in compliance with ISO 15197:2013(E) Clause 8

A study to validate the accuracy performance of the OneTouch Verio Flex Blood Glucose Monitoring System in the hands of the Lay user in accordance with ISO 15197:2013(E) Clause 8 was undertaken. A comparison of the Lay User OneTouch Verio Flex 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 by 167 lay persons showed the following results:
93.1% within ±15mg/dl of the glucose reference (YSI) values at glucose concentrations below 100mg/dL and 98.6% within ±15% of the medical laboratory values at glucose concentrations at or above 100mg/dL.
97.6% of the total number of samples across the entire glucose range were within ±15 mg/dl or ±15% of the medical laboratory values.

Subject Fingertip Results for Glucose Concentrations <100 mg/dL

Percent (and number) of meter results that match the YSI reference

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
72.4%	93.1%	93.1%
(21/29)	(27/29)	(27/29)

Subject Fingertip Results for Glucose Concentrations ≥100 mg/dL

Percent (and number) of meter results that match the YSI reference

Within ±5%	Within ±10%	Within ±15%
58.7%	88.4%	98.6%
(81/138)	(122/138)	(136/138)

Results for Glucose concentrations across the glucose range:

Percent (and number) of meter results that match the YSI reference

Within ±15 mg/dL (±0.83 mmol/L) or ±15%
97.6% (163/167)

Summary

Design verification and validation testing confirmed that the performance, safety, and effectiveness of the OneTouch® VerioFlex™ 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. The OneTouch Verio Flex Meter also meets the requirements of ISO15197:2013 and applicable recognized electrical and safety standards including FCC requirements.

Conclusions

The OneTouch®Verio Flex™ 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™ Blood Glucose Monitoring System (K131363).