



LIFESCAN EUROPE
NIKI SKELLY
REGULATORY AFFAIRS CONSULTANT
BEECHWOOD PARK NORTH
INVERNESS, SCOTLAND IV2 3ED, GREAT BRITAIN

December 14, 2015

Re: K151611

Trade/Device Name: OneTouch Ultra Plus Flex Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: November 17, 2015
Received: November 20, 2015

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. 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,


Katherine Serrano -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

Enclosure

Indications for Use

510(k) Number (if known)

K151611

Device Name

OneTouch Ultra Plus Flex Blood Glucose Monitoring System

Indications for Use (Describe)

The OneTouch Ultra Plus 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 Ultra Plus Flex Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

OneTouch Ultra Plus 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 Ultra Plus Flex Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes, or for neonatal use.

The OneTouch Ultra Plus Test Strips are for use with the OneTouch Ultra Plus 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
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Date Prepared	December 11 th 2015
Device Trade Name	OneTouch Ultra Plus Flex Blood Glucose Monitoring System
Common Name	Glucose Test System
Classification	OneTouch Ultra Plus Flex Blood Glucose Meters and OneTouch Ultra Plus Test Strips are Class II devices (21 CFR § 862.1345), Product Code NBW, LFR
System Description	The OneTouch Ultra Plus Flex Blood Glucose Monitoring System consists of the OneTouch Ultra Plus Flex Blood Glucose Meter, OneTouch Ultra Plus Test Strips, OneTouch Ultra Plus Level 3 and Level 4 Control Solutions, Lancing Device and Sterile Lancets. The

	<p>OneTouch Ultra Plus 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.</p>
<p>Predicate Device</p>	<p>OneTouch[®] Verio[™] Blood Glucose Monitoring System (K131363, Cleared 30th August 2013)</p>
<p>Intended Use/Indications for Use</p>	<p>The OneTouch Ultra Plus 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 Ultra Plus Flex Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.</p> <p>The OneTouch Ultra Plus 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 Ultra Plus Flex Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes, or for neonatal use.</p> <p>The OneTouch Ultra Plus Test Strips are for use with the OneTouch Ultra Plus Flex Blood Glucose Meter to quantitatively measure glucose drawn from the fingertips.</p>
<p>Comparison to Predicate Device</p>	<p>The Subject device is different from the predicate device in the following aspects:</p> <ul style="list-style-type: none"> • Meter: <ul style="list-style-type: none"> ○ Ergonomic/physical design: Changes to size, shape and color ○ Electronic/hardware: Modified Strip Port Connector and addition of wireless communications facility ○ Software/Firmware changes: Modified Blood Glucose Algorithm and addition of a range indicator software feature • Labelling:

	<ul style="list-style-type: none"> ○ New branding and Instructions for Use for Meter, Test Strips and Control Solutions ● Strip: <ul style="list-style-type: none"> ○ Change to color of spacer layer ○ Laser line on left strip leg to align with new Strip Port Connector <p>The only change to the Control Solutions cleared for use with the predicate OneTouch® Verio™ Blood Glucose Monitoring System 510(k) (K131363) as OneTouch Verio Control Solutions Level 3 (Mid) and Level 4 (High) is that a new brand name of OneTouch Ultra Plus Level 3 (Mid) and Level 4 (High) Control Solutions will be used to align branding with the new system; the formula is identical to the cleared Control Solution. The OneTouch Verio Control Solutions will continue to be marketed with the associated cleared BGMS.</p> <p>There have been no changes to the intended use, operating principle or scientific technology.</p>
<p>Technological Characteristics</p>	<p>There has been no change to the fundamental scientific technology, which is amperometric detection. The operating principle remains electrochemical reaction.</p>
<p>Summary of Performance Characteristics</p>	<p>The OneTouch Ultra Plus 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 interference, 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 Ultra Plus Flex Blood Glucose Monitoring System performed similarly to both the predicate device and a laboratory reference method, the Yellow Springs Instrument (YSI).</p>

Interference Performance

The maximum allowed concentration of every potentially interfering substance was tested in a study (i.e. the highest concentration tested that would not compromise system response of the OneTouch Ultra Plus Flex System). Samples with 2 levels of glucose 70 and 300mg/dL were tested by spiking with potentially interfering substances at 4 concentrations, each sample was analyzed by the OneTouch Ultra Plus Flex meter. Test results of the spiked samples were compared with results from control samples without potential interfering substances and the difference between the 2 samples was calculated. The results in the table below are within $\leq 10\%$ of the control sample.

Interferent	Maximum Allowed Concentration (mg/dL)	Does the Maximum Allowed Concentration exceed the High Normal/Therapeutic Endogenous Concentration?
Acetaminophen	10.89 ²	Yes
Ascorbic Acid	6.38	Yes
Bilirubin	20.53	Yes
Cholesterol	794.4	Yes
Creatinine	31.83	Yes
Dopamine	0.051 ²	Yes
EDTA	0.10	Yes
Ephedrine	0.21	Yes
Galactose	60.39	Yes
Gentisic Acid	1.85	Yes
Glutathione	92.61	Yes
Haemoglobin	237.6	Yes
Heparin	2.15	Yes
Ibuprofen	50.52	Yes
Icodextrin	1241.72	Yes

Interferent	Maximum Allowed Concentration (mg/dL)	Does the Maximum Allowed Concentration exceed the High Normal/Therapeutic Endogenous Concentration?
Lactose	4.25	Yes
L-Dopa (Levo-Dopa)	1.01	Yes
Maltose	363.60	Yes
M-Dopa (Methyl-Dopa)	1.50	Yes
Pralidoxime Iodide (PAM)	OneTouch Ultra Plus Flex Blood Glucose Monitoring system not to be used with patients undergoing PAM treatment	No OneTouch Ultra Plus Flex SMBG system is not to be used with patients undergoing PAM treatment: Caution included in product labelling ⁴
Salicylic Acid	58.90	Yes
Tetracycline	1.52	Yes
Tolazamide	15.03	Yes
Tolbutamide	65.98	Yes
Triglycerides	3431.11	Yes
Urea	297.55	Yes
Uric Acid	8.1¹	Yes

Interferent	Maximum Allowed Concentration (mg/dL)	Does the Maximum Allowed Concentration exceed the High Normal/Therapeutic Endogenous Concentration?
Xylose	8.09	<p style="text-align: center;">No</p> <p style="text-align: center;">OneTouch Ultra Plus Flex SMBG system is not to be used with patients undergoing xylose absorption treatment:</p> <p style="text-align: center;">Caution included in product labelling³</p>

Based on the results in this table, interferent limitations identified in labeling are noted below

^{1 2 3 4}
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¹ Uric acid at concentrations greater than 8mg/dL can interfere with glucose measurements.

² Drugs containing acetaminophen (e.g Tylenol etc.) or Dopamine at doses higher than the recommended high therapeutic level, may result in inaccurate readings from the OneTouch Ultra Plus Flex™ blood glucose monitoring system.

³ The OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System should not be used within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results.

⁴ The OneTouch Ultra Plus Flex™ Meter should not be used when PAM (Pralidoxime) is known or suspected to be in the whole blood sample.

Method Comparison Performance

A study evaluating the glucose values from the OneTouch Ultra Plus 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 113 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
71.7% (43/60)	95.0% (57/60)	100% (60/60)

Method Comparison Results for Glucose Concentrations ≥ 75 mg/dL

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

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
61.3% (171/279)	89.6% (250/279)	98.6% (275/279)	100% (279/279)

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 $\pm 15\%$
97.9% (332/339)

A linear regression analysis of the method comparison study indicates that the OneTouch Ultra Plus Flex Blood Glucose Monitoring System compared well to the laboratory reference instrument (YSI analyzer). Comparison of the OneTouch Ultra Plus Flex Blood Glucose Monitoring System (subject device) and OneTouch Verio Blood Glucose Monitoring System (predicate device), based on the difference between the proportions of results within ± 10 mg/dl or $\pm 15\%$ of the corresponding reference values, indicates that the subject device and the predicate device are substantially equivalent.

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 #	# Participants/ tests	Slope [95% CI]	Intercept [95% CI] (mg/dL)	Std. Error ($S_{y,x}$) (mg/dL)	R ²
OneTouch Verio	D	113	0.98 [0.96 to 1.00]	4.86 [1.10 to 8.61]	10.6	0.99
OneTouch Ultra Plus Flex	A	113	1.02 [1.00 to 1.05]	-2.16 [-6.66 to 2.33]	12.7	0.99
	B	113	0.99 [0.97 to 1.01]	-1.54 [-5.37 to 2.30]	10.8	0.99
	C	113	1.01 [0.99 to 1.02]	-2.33 [-5.94 to 1.27]	10.2	0.99
	3 lots	339	1.01 [1.00 to 1.02]	-2.01 [-4.35 to 0.33]	11.5	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 Ultra Plus Flex Blood Glucose Monitoring System in the hands of the user was conducted. A comparison of the Lay User OneTouch Ultra Plus 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 169 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
75.0%	90.0%	95.0%
(15/20)	(18/20)	(19/20)

Subject Fingertip Results for Glucose Concentrations ≥ 75 mg/dL
 Percent (and number) of meter results that match the YSI reference

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
63.1%	88.6%	96.0%	100%
(94/149)	(132/149)	(143/149)	(149/149)

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

Within ± 10mg/dL or $\pm 15\%$
95.3%
(161/169)

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	19.39	0.55	2.86
40	34.98	0.86	2.46
90	98.81	1.89	1.91
130	139.26	2.95	2.11
200	222.32	4.28	1.92
350	382.15	8.14	2.13
600	641.27	13.51	2.11

Results show that the greatest variability observed between test strips when tested with blood is 1.89mg/dl SD or less at glucose levels less than 100mg/dl, or 2.13% 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)	12.39	0.47	3.76
Low (25 – 49)	36.87	0.97	2.62
Mid (102 – 138)	117.98	2.19	1.86
High (298 – 403)	352.03	7.92	2.25
Very High (446-604)	520.56	12.60	2.42

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 ± 15 mg/dl of the medical laboratory values at glucose concentrations below 100mg/dL and 100%, 98.6%, 97.8% 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 ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
A	61.3% (38/62)	91.9% (57/62)	100% (62/62)
B	71.0% (44/62)	96.8% (60/62)	100% (62/62)
C	66.1% (41/62)	93.5% (58/62)	100% (62/62)
Pooled Results for Lots A-C	66.1% (123/186)	94.1% (175/186)	100% (186/186)

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 $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
A	65.9% (91/138)	92.0% (127/138)	100% (138/138)
B	60.9% (84/138)	92.8% (128/138)	98.6% (136/138)
C	67.4% (93/138)	93.5% (129/138)	97.8% (135/138)
Pooled Results for Lots A-C	64.7% (268/414)	92.8% (384/414)	98.8% (409/414)

System accuracy results across the glucose range tested: concentrations between 36.7 to 507.3 mg/dL

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

Test Strip Lot Number	Within ± 15 mg/dL or $\pm 15\%$
A	100% (200/200)
B	99.0% (198/200)
C	98.5% (197/200)
Pooled Results for A-C	99.2% (595/600)

NOTE: Where 36.7 mg/dL represents the lowest glucose reference value and 507.3 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 Ultra Plus Flex Blood Glucose Monitoring System in the hands of the Lay User in accordance with ISO 15197:2013(E) Clause 8 was performed. A comparison of the Lay User OneTouch Ultra Plus Flex Blood Glucose Monitoring System fingertip results to the 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 166 lay persons showed the following results:

96.8% within ± 15 mg/dl of the glucose reference (YSI) values at glucose concentrations below 100mg/dL and 97.0% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 100mg/dL.

97.0% of the total number of samples across the entire glucose range were within ± 15 mg/dl or $\pm 15\%$ 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
71.0%	87.1%	96.8%
(22/31)	(27/31)	(30/31)

Subject Fingertip Results for Glucose Concentrations ≥ 100 mg/dL

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

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
65.2%	89.6%	97.0%
(88/135)	(121/135)	(131/135)

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 $\pm 15\%$
97.0%
(161/166)

Summary

Design verification and validation testing confirmed that the performance, safety, and effectiveness of the OneTouch Ultra Plus Flex 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 Ultra Plus Flex System also meets the requirements of ISO15197:2013 and applicable recognized electrical and safety standards including FCC requirements.

Conclusions

The OneTouch Ultra Plus 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).