k093745

510(K) SUMMARY

FEB 11 2011

SPONSOR

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CORRESPONDENT

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DEVICE NAME AND CLASSIFICATION

Trade Name: OneTouch® Verio™ Blood Glucose Monitoring System
Common name: Glucose test system
Classification:
OneTouch® Verio™ 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

SYSTEM DESCRIPTION

The OneTouch® Verio™ Blood Glucose Monitoring System consists of the OneTouch® Verio™ Meter, OneTouch® Verio™ Test Strips, OneTouch® Verio™ Control Solutions (mid and high levels), the Lancing Device, Sterile Lancets and Clear Cap (sold separately). The OneTouch® Verio™ 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 DEVICES

OneTouch® Ultra®2 Blood Glucose Monitoring System (K053529)
OneTouch® Select™ Control Solutions (K072543)

INTENDED USE/INDICATIONS FOR USE

The OneTouch® Verio™ 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, forearm or palm. The OneTouch® Verio™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The OneTouch® Verio™ 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™ Blood Glucose Monitoring System should not 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™ Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The OneTouch® Verio™ Control Solutions are for use with the OneTouch® Verio™ Blood Glucose Meter and Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

COMPARISON TO PREDICATE DEVICES

The Subject device is different from the predicate device for the following aspects:

- Meter: ergonomic/physical design, user interface, hardware, modified electronic and software changes.
- Test Strip: materials of construction, physical layout of the strip electrodes, enzyme chemistry, calibration coding and sample application location.
- Control Solution: glucose nominal levels, composition and color of control solutions.

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; however the Subject device uses Glucose Dehydrogenase and the predicate device uses Glucose Oxidase as the reagent.

SUMMARY OF PERFORMANCE CHARACTERISTICS

The OneTouch® Verio™ Blood Glucose Monitoring System (meter, strips, and control) was tested in accordance with ISO 15197:2003(E). Analytical performance testing included system accuracy, repeatability and intermediate precision testing. A user performance evaluation assessed accuracy of results and usability of the device in the hands of intended users. The OneTouch® Verio™ Blood Glucose Monitoring System performed similarly to both the predicate device as well as to a laboratory reference method, the Yellow Springs Instrument (YSI).

System Accuracy

A comparison of system accuracy performance demonstrated that the OneTouch® Verio™ Blood Glucose Monitoring System and the currently marketed OneTouch® Ultra®2 Meter are substantially equivalent.

System Accuracy Results for Glucose Concentrations <75 mg/dL

Percent (and number) of meter results that match the laboratory test

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
78/96 (81.3%)	92/96 (95.8%)	96/96 (100.0%)

System Accuracy Results for Glucose Concentrations ≥75 mg/dL

Percent (and number) of meter results that match the laboratory test

Within ±5%	Within ±10%	Within ±15%	Within ±20%
318/504 (63.1%)	464/504 (92.1%)	499/504 (99.0%)	503/504 (99.8%)

Regression Statistics

Samples were tested in duplicate on three test strip lots. Results indicate that the OneTouch® Verio™ System compares well with a laboratory method.

# of Subjects	# of Tests	Slope	Intercept (mg/dL)
100	600	0.994	-0.204

95% CI Slope	95% CI Intercept	Std. Error ($S_{y.x}$)	R^2
0.986 to 1.003	-1.971 to 1.564	11.554	0.988

Precision

Within Run Precision (300 Venous Blood Tests)

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	39.37	1.07	2.72
100	100.58	1.75	1.74
130	126.12	2.41	1.91
200	189.24	3.36	1.78
350	323.63	6.65	2.05

Results show that the greatest variability observed between test strips when tested with blood is 2.72% or less.

Total Precision

(600 Control Solution Tests)

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Low (38-62)	50.66	1.28	2.53
Mid (102-138)	116.51	2.89	2.48
High (298-403)	350.02	7.7	2.2

User Performance Evaluation

Subject and HCP Fingertip Results for Glucose Concentrations <75 Mg/dL

Tester	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Subject	21/28 (75%)	28/28 (100%)	28/28 (100%)
HCP	16/28 (57.1%)	24/28 (85.7%)	28/28 (100%)

Subject and HCP Fingertip Results for Glucose Concentrations ≥75 Mg/dL

Tester	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Subject	68/128 (53.1%)	115/128 (89.8%)	127/128 (99.2%)	128/128 (100%)
HCP	74/125 (59.2%)	109/125 (87.2%)	120/125 (96.0%)	124/125 (99.2%)

Alternate Site Testing

Subject AST Results for Glucose Concentrations <75 mg/dL

Site	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Palm	6/8 (75.0%)	8/8 (100%)	8/8 (100%)
Forearm	4/7 (57.1%)	6/7 (85.7%)	7/7 (100%)

Subject AST Results for Glucose Concentrations ≥75 mg/dL

Site	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Palm	80/154 (51.9%)	132/154 (85.7%)	146/154 (94.8%)	150/154 (97.4%)
Forearm	66/144 (45.8%)	110/144 (76.4%)	127/144 (88.2%)	138/144 (95.8%)

Design verification and validation testing confirmed that the performance, safety, and effectiveness of the OneTouch® Verio™ Blood Glucose Monitoring System were equivalent to that of the predicate device. The OneTouch® Verio™ Meter met recognized electrical and safety standards.

CONCLUSIONS

The OneTouch® Verio™ Blood Glucose Monitoring System is substantially equivalent in its intended use, performance, safety, effectiveness and the underlying scientific and operating principles used, to the predicate OneTouch® Ultra®2 Blood Glucose Monitoring System (K053529), and OneTouch® Select™ Control Solutions (K072543).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 11 2011

Life Scan, Inc.
c/o Ms. Lisa McGrath
Regulatory Project Manager/Global Regulatory Affairs
1000 Gibraltar Drive, MS 2C
Milpitas, CA 95035-6312

Re: k093745
Trade Name: One Touch Verio Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System.
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: February 8, 2011
Received: February 9, 2011

Dear Ms. McGrath:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K093745

Device Name: OneTouch® Verio™ Blood Glucose Monitoring System

Indications for Use:

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The OneTouch® Verio™ 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™ Blood Glucose Monitoring System 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).

The OneTouch® Verio™ Test Strips are for use with the OneTouch® Verio™ Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The OneTouch® Verio™ Control Solutions are for use with the OneTouch® Verio™ Blood Glucose Meter and Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use ___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _X_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

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