510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:
    k120558

B. Purpose for Submission:
    This is a New Diabetes Data Manager for use with OneTouch® Verio Sync Blood
    Glucose Monitoring System (k120708).

C. Manufacturer and Instrument Name:
    LIFESCAN, Inc.

    OneTouch® Reveal Diabetes Management Application

D. Type of Test or Tests performed:
    Diabetes data management system

E. System Descriptions:
    Device Description:
        The OneTouch® Reveal Diabetes Management Application (App) is a
        diabetes management tool that can help the user determine what blood glucose
        test results mean. This allows the user and their health care professional to
        better monitor and adjust their diabetes care plan. The App is designed to
        work in conjunction with the OneTouch® Verio™ Sync Meter. Using the
        Bluetooth® feature on the OneTouch® Verio™ Sync meter and Apple® device,
        blood sugar test results can be sent directly from the meter to the App.

    Principles of Operation:
        The OneTouch® Reveal Diabetes Management Application has a software
        feature that alerts users to low and high blood glucose patterns. This software
        feature has also been implemented on another cleared LifeScan blood glucose
        meter, the One Touch Verio IQ Blood Glucose Meter.

        The OneTouch® Reveal™ Application (App) is designed to run under Apple
        iOS 4+ operating systems on the following devices:
        • iPhone 4 and iPhone 3GS
        • iPod Touch 3rd and 4th Gen
        • iPad 1st and 2nd Gen

        The App stores blood glucose test results, events and user settings. The App's
        memory capacity is 2500 blood glucose results and events; and is limited to a
        maximum of 1 year of results and events. In addition to receiving blood
        glucose measurement readings from the OneTouch Verio Sync Meter via

Bluetooth, storing and displaying them, the App provides the following features and tools for the user:

- Time Synchronization: Synchronizing the time between the App and the OneTouch Verio Sync Meter.
- Tagging of Results: Allows quick settings of meal tags and notes to results just downloaded from the meter.
- Pattern Messages: Alerts the user that one or more patterns were found in the results that were downloaded.
- Events: Allows the user to manually enter data, such as: manual blood glucose results, carbohydrates consumed, activity performed and medications taken.
- Sharing: Allows the user to share blood glucose results via SMS text or email.

Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer webserver, or mobile device? Yes _X_ or No _____.

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission: Yes _X_ or No ____.

Specimen Identification:

Specimen identification is based on time and date of testing.

Specimen Sampling and Handling:

Data transmission from glucose meters using capillary whole blood samples

Calibration:

Glucose meter specific. See statement below under section J.

Quality Control:

Glucose meter specific. See statement below under section J.

Software:

FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes _X_ or No _____

F. Regulatory Information:

Device Name	Product Code	Classification	Regulatio	Panel
Glucose Test System	NBW: Blood Glucose Test System, Over-the- Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Calculator/Data Processing Module for Clinical Use	JQP: Calculator/ Data Processing Module for Clinical Use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:
   The OneTouch® Reveal Diabetes Management Application is a software accessory to the OneTouch® Verio Sync Blood Glucose Monitoring System, and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management. The OneTouch® Reveal Diabetes Management Application receives (from both manual entry and wireless transmission), stores, and sends patient data for display and reporting. The OneTouch® Reveal Diabetes Management Application also communicates with web-based applications. The OneTouch® Reveal Diabetes Management Application is available for use on commercially-available mobile devices and uses generally available networks and communication protocols.

2. Special conditions for use statement(s):
   Over-the-counter use

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
   WellDoc Diabetes Manager System k100066

2. Comparison with Predicate Device:

Similarities and Differences		
Item	Candidate Device **OneTouch® Reveal Diabetes Management Application**	Predicate Device (k100066)
Intended Use	The OneTouch® Reveal Diabetes Management Application is a software accessory to the OneTouch®	Same

	Verio Sync Blood Glucose Monitoring System, and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management.	
Over-the-Counter	Yes	Same
Accessory to Glucose meter	Yes	Same
Intended user	Home Users/HCPs	Same
Components	Mobile Based Application	Same
Setting Reminders	Yes	Same
Connectivity to Meter	Bluetooth	Same
Manual Data Entry	Yes	Same
Logbook	Yes	Same
Messaging	Yes	Same

I. Standard/Guidance Document Referenced (if applicable):
None referenced

J. Performance Characteristics:
The performance characteristics listed below as applicable, are presented in the specific glucose clearance under k120708.

- Analytical Performance:
  The performance characteristics listed below as applicable, were presented in the specific glucose meter clearance under k120708
    a) *Accuracy:*
       See above statement under section J(1).

    b) *Precision/Reproducibility:*
       See above statement under section J(1).

    c) *Linearity:*
       See above statement under section J(1).

    d) *Carryover:*
       See above statement under section J(1).

    e) *Interfering Substances:*
       See above statement under section J(1).

2. Other Supportive Instrument Performance Data Not Covered Above:

a) A usability study was performed with One hundred sixty-eight (168) subjects, including 21 pediatric Subjects (ages 12 to 18 years). The study was conducted at two clinical sites. Each subject attended two site visits, with a home testing period between the visits.

During Site Visit 1:

The HCP issued a Home Testing Kit to the Subject and briefed the Subject on the study procedures and requirements but provided no training on the OneTouch® Verio BGMS or OneTouch® VerioOneTouch® Reveal Diabetes Management Application. The subject demonstrated (without guidance from the HCP) the ability to pair and sync the OneTouch® Verio meter and the iPod Touch using the labeling. The HCP and Subject scheduled a date and time for Site Visit 2 to complete the study.

During the home testing period (5-7 calendar days), the Subject performed the activities specified on the Home Testing Form using the OneTouch® Verio BGMS, OneTouch® Reveal Diabetes Management Application, and labeling.

During Site Visit 2:
- Orientation – The Subject familiarized himself/herself with the use of the OneTouch® Verio App "Share" feature in the OneTouch® Verio Application according to the Orientation Testing Form.
- Instructions for Use – The Subject completed two self-administered instructions for use questionnaires (Meter Instructions for Use Questionnaire and App Instructions for Use Questionnaire).
- Human Factors Assessments – The Subject performed HF tasks; an HCP observed and evaluated the Subject's technique and recorded the results on the Human Factors Assessment Form.
- Subject Feedback – The Subject completed a self-administered User Acceptance Questionnaire regarding ease of use and other HF aspects of the OneTouch® Verio BGMS and OneTouch® Reveal Diabetes Management Application.
- Subjects were briefed on study procedures and requirements but received no training on use of the OneTouch® Verio BGMS or OneTouch® Reveal Diabetes Management Application.

Lay User Human Factors Assessments – The success rates for all 44 assessments on the Human Factors Assessment Form meet the assigned risk-based acceptance criteria of better than 93.8% success,

thus validating the critical areas to test that are the basis for those assessments.

Lay User Feedback – The proportions of neutral-or-better responses for all 21 items on the User Acceptance Questionnaire meet the acceptance criterion of meeting better than 81.0% of neutral-or-better feedbacks, thus validating the critical areas to test that are the basis for those questionnaire items.

b) Software installation, connectivity and data transmission as intended to be use, was assessed and verified to achieve 100% accuracy for data transmission.

c) Bench Testing was performed on data from one meter to test meter memory rollover and data transmission, this included full memory data transmission, plus additional data to validate correct data rollover in the app. All data fields were 100% accurate.

d) The app has the function of being able to link to more than one meter. The applicant tested 8 meters for configuration syncing and data transmission. All data fields were 100% correct.

e) Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.

f) The sponsor provided the results of a Flesch-Kincaid readability study which indicated a Grade Level Score of 7.8 for the OneTouch® Reveal Diabetes Management Application and owner's booklet.

g) The sponsor provided third party device conformity to EMC standards related to Radio Frequency Fields from Hand-Held and Body-Mounted Wireless Communication Devices for Specific Absorption Rate (SAR), and Information Technology Equipment Safety.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.