510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k172723

B. Purpose for Submission:

Device modification to change the connector of the Dario meter from 3.5mm Audio Jack Plug to an Apple Lightning Connector

C. Measurand:

Glucose in capillary whole blood obtained from fingertips

D. Type of Test:

Quantitative, amperometric method

E. Applicant:

LabStyle Innovations.

F. Proprietary and Established Names:

Dario LC Blood Glucose Monitoring System.

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, blood glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, System, Test, Blood Glucose, Over the Counter

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below

2. Indication(s) for use:

   The Dario LC Blood Glucose Monitoring System consists of the Dario LC Blood Glucose Meter, Dario Glucose Test Strips, Dario Glucose Control Solutions and the Dario App as the display component of the Dario LC Blood Glucose Monitoring System. The Dario LC Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The Dario LC Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

   The Dario LC Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. The Dario LC Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

   The Dario Blood Glucose Test Strips are for use with the Dario LC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

3. Special conditions for use statement(s):

   - For Over-the-Counter use
   - Single-patient use only
   - Not for testing glucose levels of neonates
   - Not for the diagnosis of, or screening for, diabetes
   - Not for testing glucose levels of arterial or venous blood
   - Not for testing glucose from sites other than the fingertip
   - Not for testing patients who are critically ill, in shock, dehydrated or hyperosmolar
   - This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

4. Special instrument requirements:

   Dario LC Blood Glucose Meter
   Apple Smart Mobile Device (5, 5S, 5C, 6, 6 Plus, 6S, 6S Plus, 7 and 7 Plus) with iOS 7, 8, 9, and 10.

I. Device Description:

The Dario LC Blood Glucose Monitoring System consists of the Dario LC Blood Glucose meter, 25 Dario Test Strips housed in a disposable cartridge (sold separately), lancets (sold separately), Dario Control Solution Levels 1 and 2 (sold separately), Disposable Covers for the mobile devices (also sold separately), User Manual and Quick User Guide, the Dario Application Software (needs to be downloaded from the Apple App Store). The Dario LC BGMS can be used with Apple platform smart mobile devices (5, 5S, 5C, 6, 6 Plus, 6S, 6S Plus, 7 and 7 Plus), with operating system versions iOS 7, 8, 9, and 10.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dario Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

   k150817

3. Comparison with predicate:

Item	Dario LC Blood Glucose Monitoring System (Candidate Device)	Dario Blood Glucose Monitoring System (k150817, Predicate Device)
Indication For Use	Intended for the quantitative measurement of glucose in fresh capillary whole blood samples by people with diabetes at home to monitor the effectiveness of diabetes control.	Same
Assay Detection Method	Amperometry	Same
Supported Smart Mobile Devices	Apple iPhone 5, 5S, 5C, 6, 6 Plus, 6S, 6S, Plus, 7 and 7 Plus with the Lightning port.	Apple iPhone 4S, 5, 5S, SE, 6, 6 Plus, 6S and 6S Plus with the Audio Jack port.
Supported Smart Mobile Device Operating Systems	Apple iOS 7, 8, 9 and 10	Apple iOS 7, 8, 9, 9.3, and 10
Primary Components	Meter , Housing and Test Strips (cartridge)	Same
Method of Connection to Smart Mobile Device	Apple Lightning Connector	3.5mm Audio Jack Plug
Memory	Unlimited results; Memory is limited to smart mobile	Same

Item	Dario LC Blood Glucose Monitoring System (Candidate Device)	Dario Blood Glucose Monitoring System (k150817, Predicate Device)
	device memory.	
Assay Method	Glucose oxidase	Same
Measuring Range	20-600 mg/dL	Same
Sample Type	Fresh capillary whole blood	Same
Sample Site	Fingertip	
Weight	40 gram (1.4 oz)	Same
Software Application	Dario App	Same
Display	Connected to smart mobile device to display measurement results, messages and error codes.	Same
Power Source	Powered by Apple Lightning Connector connected to smart mobile device.	Powered by 3.5mm Audio Jack Connector connected to smart mobile device.

K. Standard/Guidance Document Referenced (if applicable):

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, Guidance for Industry and Food and Drug Administration Staff. October 11, 2016.

CLSI EP06-A "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach"

ISO 14971: 2007 – Medical Devices Application of risk management to medical devices (EN ISO 14971:2012).

IEC 60601-1:2005, Edition 3.1 (amendment 1:2012) – Medical Electrical Equipment – Part1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-1-11:2015, Second Edition – Medical Electrical Equipment – Part1-11-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-1-2:2014, Fourth Edition – Medical Electrical Equipment – Part1-2: General Requirements for Basic Safety and Essential Performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests.

IEC 60601-1-1:2010, Edition 3.1 (amendment 1:2013) – Medical Electrical Equipment – Part1-6: General Requirements for Basic Safety and Essential Performance. – Collateral standard: Usability.

L. Test Principle:

The Dario LC System determines the amount of glucose in fresh capillary blood using electrochemical biosensor technology. An electrical current is generated by the reaction of glucose with the reagent on the test strip (glucose oxidase). The strength of the current produced by the reaction depends on the amount of glucose in the blood sample. The glucose meter detects the current and converts it into a blood glucose reading. The final results are communicated from the meter to the smart mobile device through the Apple Lightning Connector.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The Dario LC BGMS is compatible with iPhone 5, 5S, 5C, 6, 6s, Plus6 Plus, 7 and 7 Plus with operating systems iOS 7, 8, 9 and 10. The Apple iPhone5 model of smart mobile device was used as the representative mobile device for the following analytical performance studies.

a. Precision/Reproducibility:

The sponsor performed repeatability (within-run) precision studies using venous whole blood spiked to five different glucose concentration ranges (30 to 50, 51 to 110, 111 to 150, 151 to 250 and 251 to 400 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 3 test strip lots and 10 meters, for a total of 100 replicates per glucose level per test strip lot (for a total of 300 tests per each glucose level for 10 meter). Results are summarized below:

Lot 1				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	CV (%)
30 to 50	50.7	100	1.2	2.4
51 to 110	105.8	100	1.7	1.6
111 to 150	137.0	100	4.1	3.0
151 to 250	199.3	100	4.2	2.1
251 to 400	357.7	100	10.2	2.8

Lot 2				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	CV (%)
30 to 50	48.5	100	1.4	2.8
51 to 110	101.3	100	3.7	3.7
111 to 150	132.9	100	3.2	2.4
151 to 250	195.4	100	4.5	2.3
251 to 400	340.0	100	10.5	3.1

Lot 3				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	CV (%)
30 to 50	49.3	100	1.5	3.0
51 to 110	103.1	100	3.0	2.9
111 to 150	130.0	100	5.0	3.8
151 to 250	193.6	100	5.9	3.1
251 to 400	349.6	100	12.9	3.7

Intermediate (day to day) precision was evaluated using five levels of glucose control solutions (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL) over 10 days with 3 test strip lots by ten operators. For each level, on each day, 10 meters were used for testing, with 10 replicates collected per lot for a total of 30 replicates per 3 lots for each glucose level per day. Results are summarized below:

Lot 1			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	48.7	1.9	3.9
51 to 110	85.3	2.1	2.4
111 to 150	129.8	3.6	2.8
151 to 250	204.6	5.8	2.8
251 to 400	286.6	9.0	3.1

Lot 2			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	47.5	2.1	4.5
51 to 110	83.5	2.2	2.6
111 to 150	123.5	3.6	2.9
151 to 250	197.6	5.9	3.0
251 to 400	282.2	6.9	2.5

Lot 3			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	49.6	2.3	4.6
51 to 110	88.2	2.7	3.0
111 to 150	130.8	3.4	2.6
151 to 250	208.9	7.1	3.4
251 to 400	291.6	10.9	3.7

b. Linearity/assay reportable range:

Linearity testing was performed using heparinized venous whole blood samples. The evaluation was conducted with five meters and three test strip lots. Seventeen samples with the following glucose concentrations (mg/dL) were prepared: 11.5, 13.9, 34.7, 55.9, 77.1, 82.3, 97.7, 118.5, 152.3, 225.8, 295.3, 371.5, 446.8, 521.5, 568.0, 640 and 729.0 mg/dL (as established using a laboratory comparator method, the YSI 2300 analyzer). The values from the Dario LC Blood Glucose Monitoring System were compared with those obtained from the YSI-2300. Results from the regression analysis are as follows:

$y = 1.0046x + 2.6208$, $R^2 = 0.9972$

The results of the study support the sponsor's claimed glucose measurement range of 20-600 mg/dL. The system gives error messages "Hi" and "Lo" for results <20 mg/dL and >600 mg/dL, and these were validated.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

As established in k150817, the Dario LC Blood Glucose Monitoring System is traceable to NIST SRM 917b.

d. Detection limit:

See linearity study in Section M1b above.

e. Analytical specificity:

Same as provided in k150817.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

See lay user study in section M.3.c.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable.

   b. Clinical specificity:

   Not applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):

   To assess the performance of the Dario LC Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 350 lay user participants. Participants obtained and tested their own fingerstick samples with the Dario LC System. Blood glucose results from the Dario LC meter obtained by the lay user were compared to the glucose value from the YSI 2300 comparator method. The samples ranged from 24 to 479 mg/dL as measured by YSI. The results are summarized in the tables below:

   Lay-user vs. YSI:
   Results for glucose concentrations across the entire measuring range

Within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
182/350 (52.0%)	286/350 (81.7%)	337/350 (96.3%)	348/350 (99.4%)

   Results of linear regression analysis:

   $y = 0.9982x - 0.20809$, $r^2 = 0.9694$.

   The usability of the proposed Dario LC Blood Glucose Monitoring System with the Lightning connector was assessed within the User Evaluation study. The 350 subjects that participated in the lay-user accuracy study were included in the assessment and provided their feedback on a series of three questions related to the device and its labeling. The average responses rated the device and its individual components as "easy" or "very easy" and 100% of the users were able to successfully obtain a blood glucose reading when using the Dario LC Blood Glucose Monitoring System with the Lightning connector.

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

The American Diabetes Association suggests that the following expected glucose values for individuals without diabetes:

Before eating (FPG) < 100 mg/dL
Two hours after meals (OGTT) < 140 mg/dL

Reference: American Diabetes Association (2017). Standards of Medical Care in Diabetes – 2017. Diabetes Care, 40 (Supplement 1): S1-S132.

N. Instrument Name:

Dario LC Blood Glucose Meter

O. System Descriptions:

1. 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 _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required by the user of the system. The Dario meter is

automatically coded.

6. Quality Control:

   Two levels of glucose control solutions are available with this system, but are sold separately. Recommendations on when to test the control materials are provided in the labeling. The user is cautioned not to use the meter if the control result falls outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1) Hematocrit Study: As established in k150817, to support the claimed hematocrit range of 20 to 60%.

2) Altitude study: As established in k150817 to support the claims in the labeling that altitudes up to 10,000 feet (3048 meters) have no significant effect on blood glucose measurements from the Dario meter.

3) Sample volume study: As established in k150817, to support the claimed minimum sample volume of 0.3 μL.

4) Electrical Safety Testing: The sponsor provided documentation certifying that acceptable electrical safety testing had been performed and the candidate device was found compliant.

5) Electromagnetic Interference Testing: The sponsor provided documentation certifying that acceptable electromagnetic testing had been performed and the candidate device was found compliant.

6) Operating Condition Testing: The sponsor performed temperature and humidity studies using venous blood samples at five glucose concentrations (YSI glucose values approximately 51, 100.5, 200.0, 313.5, and 494.0 mg/dL) to evaluate temperatures ranging from 12±2°C to 45±2°C and relative humidity from 15±5% to 85±5%. Meter results were compared to YSI values. Seven temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, average temperature/low humidity, average temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 50 to 95°F (10 to 35°C) with relative humidity of 15 to 85%. The system gives an error message if it is operated outside the claimed operating temperature conditions.

7) The device is intended for single-patine use only. The disinfection efficacy studies were previously provided in k150817 demonstrating complete inactivation of live hepatitis B virus using the external materials comprising the the meter, test strip cartridge cap and housing with the chosen disinfectant, Super Sani-Cloth wipes with EPA registration

#9480-4. Robustness studies were performed by the sponsor demonstrating that the were no changes in performance or external materials of the Dario LC meter after 156 cleaning and disinfetion cycles using the super sani-cloth wipes The robustness studies were designed to simulate 3 years of single-patient use. The sponsor provides a disposable sleeve for use with the mobile device to be used with each tes strip. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

Q. Proposed Labeling:

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

R. Conclusion:

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