DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2015

LABSTYLE INNOVATIONS LTD.
TRACEY WIELINSKI
OFFICIAL CORRESPONDENT
3521 HATWYNN RD.
CHARLOTTE NC 28269

Re: K150817
Trade/Device Name: Dario Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: November 20, 2015
Received: November 23, 2015

Dear Tracey Wielinski:

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

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)*

K150817

Device Name

Dario Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Dario Blood Glucose Monitoring System consists of the Dario Blood Glucose Meter, Dario Glucose Test Strips, Dario Glucose Control Solutions and the Dario App as the display component of the Dario Blood Glucose Monitoring System. The Dario 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 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Dario 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 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 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(As required by 21.CFR.807.92)

1. SUBMITTER

Manufacturer: LabStyle Innovation Ltd.
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Date Prepared: December 10, 2015

2. DEVICE INFORMATION

Device Name: Dario® Blood Glucose Monitoring System

Common Name: Blood Glucose Test System

Classification Name: System, Test, Blood Glucose, Over The Counter

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1345	Class II	CGA, Glucose Oxidase, glucose	Clinical Chemistry (75)
21 CFR § 862.1345	Class II	NBW, system, test, blood glucose, over the counter	Clinical Chemistry (75)
21 CFR § 862.1660	Class I	JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)	Clinical Chemistry (75)

3. PREDICATE DEVICE

K131230 - Philosys Inc., Gmate SMART Blood Glucose Monitory System, Gmate SMART Application

4. DEVICE DESCRIPTION

The Dario Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The Dario 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 Blood Glucose Monitoring System consists of a device housing that includes a blood glucose meter and lancing device. The system also includes test strips, lancets, control solutions and a mobile application. The Dario meter does not require coding or separate batteries. The Dario meter is powered via the 3.5mm audio headphone jack of the smart mobile device. Users are instructed to insert the test strip into the meter, apply the blood or control solution to the test strip, after which the meter will process the test in approximately six (6) seconds and display the test result on the smart mobile device screen via the mobile application.

The Dario Blood Glucose Monitoring System uses Apple's iOS smart mobile device technology to view the glucose test results via a mobile application. This application is available for download via the smart mobile device's application store.

Test Principle:

The Dario Blood Glucose Monitoring System is an *in vitro* diagnostic device intended for the measurement of glucose in fresh whole capillary blood. The principle of the test relies upon a reaction between a specific type of sugar (glucose) in the blood sample and the glucose oxidase in the test strip. This reaction generates a small electrical current, which is measured by the meter. The meter calculates the blood glucose level based on an internal algorithm. The Dario application displays the test result via the smart mobile device display.

5. INDICATIONS FOR USE

The Dario Blood Glucose Monitoring System consists of the Dario Blood Glucose Meter, Dario Glucose Test Strips, Dario Glucose Control Solutions and the Dario App as the display component of the Dario Blood Glucose Monitoring System. The Dario 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 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Dario 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 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 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

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

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The indications for use and the base scientific technology of the Dario Blood Glucose Monitoring System are both similar to that of the predicate device. Both the subject device and the predicate are *in vitro* diagnostic devices intended for the measurement of glucose in capillary blood. They each use amperometry as the detection method and glucose oxidase as the enzyme in the test strip. Both the subject and predicate device use a smart mobile device to obtain power for the meter via the 3.5mm audio jack and display the blood glucose result in a mobile application.

The test principle for the Dario Blood Glucose Monitoring System and the predicate device are also similar. The principle of the test relies upon a reaction between glucose in the blood sample and the glucose oxidase in the test strip to produce a small electrical current. The meter measures this electrical current and calculates the blood glucose level via an internal algorithm. The Dario and the predicate both use the smart mobile device for the display of the results via a downloadable mobile application.

The performance testing data demonstrated that the subject device does not raise any new issues of safety and effectiveness. Therefore, based on the information provided in this submission, LabStyle Innovations concludes that the Dario Blood Glucose Monitoring System is substantially equivalent to the predicate device.

7. PERFORMANCE TESTING SUMMARY

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." The software for this device was considered as a "moderate" level of concern, since a malfunction or a latent design flaw in the software device could lead to an erroneous result or a delay in delivery of appropriate medical care that would likely lead to minor injury.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Dario Blood Glucose Monitoring System. The system complies with IEC 61010-1 and EN 61010-2-101 standards for safety and EN 61326-1 and EN 61326-2-6 standards for EMC.

The Dario Blood Glucose Monitoring System also complies with IEC 60601-1-2.

System Accuracy

System accuracy was determined according to ISO 15197:2003. The Dario Blood Glucose Monitoring System performance was assessed against a reference method. 100 samples with glucose concentrations ranging from 24 to 479 mg/dL were obtained and then tested with three (3) test strip lots and six (6) Dario meters with a total of 600 tests performed. Five (5) low concentration samples ranging of less than 50 mg/dL and five (5) high concentration samples of greater than 400 mg/dL were assessed.

The results showed that 100% of individual glucose results fell within 15 mg/dL of the YSI reference at glucose concentrations < 75 mg/dL and 99.6% of individual glucose results fell within 20% of the results of YSI at glucose concentrations ≥ 75mg/dL.

Precision/Repeatability Study

Precision was determined according to ISO 15197:2003. Within-run precision studies using venous whole blood samples spiked to five (5) different glucose concentration ranges (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL). Three (3) Dario test strips lots were tested with 10 different Dario meters and at 10 repeats, for a total of 300 results per glucose level. Between-day precision was evaluated using three (3) levels of glucose control solutions with concentrations of 30 to 50, 96 to 144, and 280 to 420 mg/dL. Per day, each sample was measured with three test strip lots and 10 meters. These tests were performed over 10 days, for a total of 300 results per glucose level.

The results for measurement repeatability and intermediate measurement precision evaluation showed a CV ≤ 4% at blood glucose concentrations ≥ 100 mg/dL and a standard deviation of ≤ 3 mg/dL at blood glucose concentrations <100 mg/dL.

Linearity Study

Linearity was determined according to ISO 15197:2003. Linearity was evaluated using six (6) test strip lots and 17 glucose concentration samples compared against the reference method measurements. Each level was measured in replicates of five (5) using three (3) test strip lots and the values from the Dario Blood Glucose Monitoring System were compared with those obtained from the reference method.

Results showed an R^2 value of 0.998, demonstrating that the Dario Blood Glucose Meter is linear over the claimed blood glucose measuring range of 20-600 mg/dL.

Hematocrit Study

The effect of different hematocrit levels on the performance of the Dario Blood Glucose Monitoring System was evaluated according to ISO 15197:2003. Venous whole blood samples with hematocrit levels of 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, and 65% spiked to three (3) glucose concentrations of 50-70, 100-200, and 250-350 mg/dL were used in the assessment. Each sample was then tested using 10 Dario Blood Glucose Meters and three (3) lots of test strips. The values were compared with those obtained from the reference method.

The % biases relative to the reference method were acceptable within the claimed hematocrit range of 20% to 60%.

Operating Conditions Study

Dario BGMS operating condition was evaluated at different temperatures and humidity levels. The combined effect of temperature and humidity were evaluated in a chamber where these conditions can be controlled. The study used five (5) meters and three (3) test strip lots. Five (5) glucose levels of venous blood samples with approximate concentrations of 60, 100, 200, 300, 480 mg/dL were tested under the following conditions:

12±2 , 15±5% (low temperature, low humidity)

12±2 , 85±5% (low temperature, high humidity)

20±2 , 15±5% (medium temperature, low humidity)

20±2 , 90% (medium temperature, high humidity)

43±2 , 15±5% (high temperature, low humidity)

43±2 , 85±5% (high temperature, high humidity)

The results demonstrated that the Dario Blood Glucose Monitoring System produces accurate results over the claimed temperature range of 50-113°F (10-45°C) and claimed humidity range of 10-90%.

Sample Volume Study

A sample volume study was performed with the Dario Blood Glucose Monitoring System to verify the test strip sample volume requirement since the Dario requires less blood to measure glucose values as compared to the predicate device. The results support the claimed sample volume of 0.3uL.

Environmental Testing

Testing was performed to test the mechanical resistance to shock, vibration and impact; equipment temperature exposure limits; and equipment humidity exposure of the Dario Blood Glucose Monitoring System. The system complies with the requirements in IEC 60068 and ISO 15197.

Disinfection Efficacy Study

A disinfection efficacy study for the exterior surfaces of the Dario Blood Glucose Meter was conducted. The results showed inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Super Sani-Cloth Wipes (EPA Registration Number 9480-4).

Cleaning and Disinfection Robustness Study

Cleaning and disinfection studies were performed demonstrating that there was no change in system performance or in the wear of the external materials of the meter and the housing after 156 cleaning and disinfection cycles designed to simulate three (3) years of single-patient device use (the life of the product). The test strips were assessed for performance impacts after a total of 25 cleaning cycles of the test strip cartridge.

Altitude Study

Capillary whole blood samples with glucose concentrations ranging between 49 to 424 mg/dL were tested on the Dario Blood Glucose Monitoring System at 10,152 feet altitude and compared to a reference method. The study evaluated three (3) different test strip lots and six (6) Dario meters.

The results demonstrate acceptable bias and indicate acceptable performance at the claimed altitude of 10,000 feet.

User Performance Study

A User Performance evaluation was performed to evaluate the accuracy of blood glucose level results obtained by users with the Dario when compared to a reference method. The secondary endpoint was to evaluate the ease of use of the subject device by lay users. Acceptance criteria were based on the requirements of ISO 15197:2003.

The results of the User Performance Evaluation study are described below:

Results for glucose concentrations less than 75 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%
4/11 (36.36%)	9/11 (81.82%)	11/11 (100%)

Results for glucose concentrations greater than or equal to 75 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
39/89 (43.82%)	68/89 (76.40%)	85/89 (95.51%)	88/89 (98.88%)

Interference Study

Interference studies on the subject device were performed by spiking venous blood with two (2) levels of glucose concentrations then testing these samples on the subject device and with a reference method. Both of the glucose spike venous samples were spiked with varying levels of potentially interfering substances, and then analyzed with the Dario Blood Glucose Meter and a reference method. The % difference between the mean of the measurements from the subject device and the reference method was then calculated. No significant interference was defined as within ± 10% difference in glucose measurement when compared to the reference methods.

The limiting concentrations of these substances have been added to the labeling and are listed below:

Compounds	**System Limitations (mg/dL)**
Ascorbic Acid	> 4
Uric Acid	> 11
Acetaminophen	> 6
Total bilirubin	> 35
Triglycerides	> 810
Cholesterol	> 455
Galactose	> 60

Ibuprofen	> 50
Lactose	> 25
Maltose	> 120
Methyl-DOPA	> 2
Xylose	> 50

Bench and Clinical Testing Summary

The design verification and validation testing of the subject device was performed in accordance with ISO 15197:2003. The Dario Blood Glucose Monitoring System met all system acceptance criteria.

8. CONCLUSION

The performance testing data demonstrates that the Dario Blood Glucose Monitoring System is substantially equivalent to the legally marketed predicate device. The Dario Blood Glucose Monitoring System does not raise any new questions of safety and effectiveness. Therefore, based on the information provided in this submission, it can be concluded that the Dario Blood Glucose Monitoring System has demonstrated substantial equivalence to the predicate device.