DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 19, 2017

LABSTYLE INNOVATIONS, LTD.
C/O TRACEY WIELINSKI, PRESIDENT
QUALTRA CONSULTING, INC.
5 CASIE LANE
PEPPERELL, MA 01463

Re: K163159
Trade/Device Name: Dario Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: June 15, 2017
Received: June 19, 2017

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 regulation (21 CFR Part 801), 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" (21CFR 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,

Kellie B. Kelm -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
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)*
K163159

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitter:	LabStyle Innovations 9 Halamish Street North Industrial Park Caesarea 3890000 Israel
Contact Person:	Tara N. Turney Regulatory Consultant Qualtra Consulting, Inc Telephone: +852-5964-8211 E-mail: tara@mydario.com
Date Prepared:	July 18, 2017
Trade Name:	Dario® Blood Glucose Monitoring System
Common Name:	Glucose Test System
Regulation:	21 § 862.1345
Product Code:	NBW
Classification Name:	System, Test, Blood Glucose, Over The Counter
Predicate Device:	Dario Blood Glucose Monitoring System K150817
Device Description:	The Dario Blood Glucose Monitoring System is a compact, all-in-one blood glucose meter that is used in conjunction with a smart mobile device (SMD). The Dario meter is connected to a SMD through a standard 3.5mm audio plug in order to provide the glucose meter with power. The SMD also provides an external display for the user to review blood glucose testing results via a mobile application downloaded to the SMD. The full process of blood glucose measurement is done on the glucose meter; the SMD does not provide any diagnostic or clinical analysis function. When connected to a SMD, the Dario glucose meter is agnostic both to the platform of the smart mobile device and to the model of the individual SMD within a platform.
Statement of Intended Use:	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 their diabetes control.

Statement of 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.

Summary of Technological Characteristics:

The proposed device has the same technological characteristics and is identical in design and configuration as compared to the predicate device.

Summary of Non-Clinical Data:

The following performance and safety testing has confirmed the proposed device to be substantially equivalent to the predicate device:

- ***In Vitro*:** the proposed Dario Blood Glucose Monitoring System has been tested for in vitro performance and meets all of its associated specifications;
- **Software:** documentation was prepared and submitted for a moderate level of concern device in accordance with FDA's Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices;*
- **Electrical Safety:** the proposed Dario Blood Glucose Monitoring System has been tested and successfully

passed all of the relevant sections of IEC 60601-1 Medical electrical equipment, General requirements for Safety;

- **Electromagnetic Interference:** the proposed Dario Blood Glucose Monitoring System has been tested and successfully met all of the relevant sections (Radiated emissions, Electrostatic discharge immunity test, radiated radio frequency, electromagnetic field immunity, and power frequency magnetic field immunity test) to satisfy compliance;

The following categories of performance were assessed and have confirmed the proposed device to be substantially equivalent to the predicate device:

- Repeatability Precision
- Intermediate Precision
- Linearity
- Operating Conditions
- Altitude
- Accuracy

Summary of Clinical Data: A User Performance study was completed for the expanded indications of the Dario Blood Glucose Monitoring System. This evaluation confirmed the proposed device to be substantially equivalent to the predicate device.

Conclusion from Data: LabStyle Innovations has demonstrated that the proposed Dario Blood Glucose Monitoring System is substantially equivalent to the predicate device based upon indications for use, design, test results and the same fundamental scientific technology.