



TAIDOC TECHNOLOGY CORPORATION
PAUL LIU
REGULATORY AFFAIRS SPECIALIST
B1-7F, NO.127, WUGONG 2ND RD., WUGU DISTRICT
NEW TAIPEI CITY 24888, TAIWAN

September 29, 2015

Re: k151100

Trade/Device Name: U-RIGHT TD-4116 Blood Glucose Monitoring System,
U-RIGHT TD-4116 Pro Blood Glucose Monitoring System

Regulation Number: 21 CFR § 862.1345

Regulation Name: Glucose Test System

Regulatory Class: II

Product Code: NBW, CGA

Dated: August 27, 2015

Received: August 31, 2015

Dear Mr. Liu:

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 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

Indications for Use

510(k) Number (if known)

k151100

Device Name

U-RIGHT TD-4116 Blood Glucose Monitoring System

Indications for Use (Describe)

The U-RIGHT TD-4116 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by a single person and should not be shared. The U-RIGHT TD-4116 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. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions (when glucose is not changing rapidly).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

k151100

Device Name

U-RIGHT TD-4116 Pro Blood Glucose Monitoring System

Indications for Use (Describe)

The U-RIGHT TD-4116 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by professionals testing with capillary whole blood samples. The U-RIGHT TD-4116 Pro Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by health care professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates. The system is only used with single-use, auto-disabling lancing devices. The alternative site testing in this system can be used only during steady-state blood glucose conditions (when glucose is not changing rapidly).

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)

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K151100

1. Submitter Information

Company Name: TaiDoc Technology Corporation
Contact Person: Paul Liu
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Prepared Date: September 28th, 2015

2. Device name:

Proprietary Name: U-RIGHT TD-4116 Blood Glucose Monitoring System
U-RIGHT TD-4116 Pro Blood Glucose Monitoring System
Common Name: Blood Glucose Monitoring System
Product Code: NBW, Blood Glucose Test System, Over-the-Counter CGA, Glucose Oxidase
Classification Panel: Clinical chemistry
Classification: Class II
Regulation Citation: 21 CFR §862.1345, Glucose test system

3. Predicate Device

Proprietary Name: U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System
Common Name: Blood Glucose Monitoring System
510(k) Number: K090188

4. Intended Use

U-RIGHT TD-4116 Blood Glucose Monitoring System:

The U-RIGHT TD-4116 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by a single person and should not be shared. The U-RIGHT TD-4116 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. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions (when glucose is not changing rapidly).

U-RIGHT TD-4116 Pro Blood Glucose Monitoring System:

The U-RIGHT TD-4116 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by professionals testing with capillary whole blood samples. The U-RIGHT TD-4116 Pro Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by health care professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates. The system is only used with single-use, auto-disabling lancing devices. The alternative site testing in this system can be used only during steady-state blood glucose conditions (when glucose is not changing rapidly).

5. Device Description:

The system consists of blood glucose meter and test strips. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. And, use only U-RIGHT TD-4116 test strips with the U-RIGHT TD-4116 Blood Glucose Monitoring System. Use only U-RIGHT TD-4116 Pro test strips with the U-RIGHT TD-4116 Pro Blood Glucose Monitoring System.

6. Comparison to the Predicate:

Comparison of Blood Glucose Meters

Item	Predicate device	Proposed device
Code calibration	No coding	Same as predicate
Measurement unit	mg/dL	Same as predicate
Measurement mode	General and QC (quality control)	General, AC, PC and QC (quality control)
Communication	Interface cable	Same as predicate
Power source	Two 1.5V AAA batteries	One 1.5V AAA battery
Memory Capacity	450 Memory Sets	Same as predicate
Time to Power saving	180 Seconds	Same as predicate
Daily Alarm	No Daily Alarm	4# Daily Alarm
Speaking function	Yes	No
Time to Power saving	180 Seconds	Same as predicate
Meter Storage /Transportation condition	-4°F - 140°F (-20°C - 60°C)	Same as predicate
Dimensions (mm):	96mm(L) x 45mm(W) x 23mm(H)	89mm(L) x 52mm(W) x 17mm(H)
Weight(g)	71g without Battery	47g without Battery

Comparison of Test Strips

Item	Predicate device	Proposed device
Enzyme	Glucose oxidase	Same as predicate
Sample volume	0.7 µL	Same as predicate
Reaction time	7 seconds	Same as predicate
Measurement method	Amperometric biosensor	Same as predicate
Measuring range	20-600 mg/dL	Same as predicate
Hematocrit range	20 – 60 %	Same as predicate
Sample type	Capillary whole blood	Same as predicate
AST	Palm, forearm, upper-arm, calf and thigh	Palm, forearm and upper arm
Strip vial opened use time	3 months	6 months

Item	Predicate device	Proposed device
Operating condition	50°F - 104°F (10°C-40°C)	Same as predicate
Storage/Transportation condition	50°F - 104°F (10°C-40°C)	Same as predicate

7. Test Principle:

The blood glucose is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter utilizes the current signal to calculate the blood glucose level.

8. Performance Characteristics:

Clinical and Non-clinical studies were conducted to evaluate the performance of the modified device. The data from these studies demonstrates that the proposed device is substantially equivalent to the predicate device.

9. Traceability:

U-RIGHT TD-4116 Blood Glucose Monitoring System and U-RIGHT TD-4116 Pro Blood Glucose Monitoring System are compared to the YSI 2300 Glucose Analyzer in the clinical and non-clinical studies. The YSI is calibrated with NIST (SRM) 917A reference material.

10. Conclusion:

Based on the information provided in this submission, the U-RIGHT TD-4116 Blood Glucose Monitoring System and U-RIGHT TD-4116 Pro Blood Glucose Monitoring System are substantially equivalent to the predicate U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System.