K113135

510(k) Summary

A summary of 510k safety and effectiveness information in accordance with 21 CFR 807.92

Date Prepared:	November 5, 2013
Sponsor Information:	UniStrip Technologies, LLC.
Sponsor Address:	2701-A Hutchison McDonald Road Charlotte, NC 28269
Sponsor Contact:	Richard Admani
Sponsor Tel Number:	1-704-285-6400
Sponsor Fax Number:	1-704-285-6495
Device Name:	UniStrip1™ Test Strips
Common/Usual Name:	Blood Glucose Test Strips
Classification Name:	Glucose, Oxidase, Glucose
Regulation Number:	21 CFR 862.1345
Product Code:	NBW, CGA
Device Class:	Class II
Review Panel:	Clinical Chemistry

NOV 0 6 2013

Predicate Device:

Manufacturer	Brand Name	510(k) Number
Lifescan, Inc.	OneTouch® Test Strips	K923544

Device Description

The UniStrip1™ Test Strips are used with the OneTouch® Ultra®, OneTouch® Ultra2®, OneTouch® UltraMini® and OneTouch® UltraSmart® blood glucose monitoring systems. The UniStrip1™ test Strips is intended for use outside the body (in vitro diagnostic use) by people with diabetes using the OneTouch® Ultra®, OneTouch® Ultra2®, OneTouch® UltraMini® and OneTouch® UltraSmart® blood glucose monitoring systems as an aid to monitor the effectiveness of diabetes control. The UniStrip1™ Test Strips allow alternate site testing (AST) from the fingertip, palm and/or the forearm. (Use of palm AST is not to be done with OneTouch® Ultra® meter).

The UniStrip1™ Test Strip can only be used on the OneTouch®Ultra®, OneTouch®Ultra2®, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before October 2012. UniStrip1™ Test Strips are only for use with calibration code 49.

Indications for Use

The Unistrip1™ Test Strips are used with the OneTouch® Ultra®, OneTouch® Ultra2®, OneTouch® UltraMini® and One-Touch® UltraSmart® meters purchased before October 2012, set at calibration code 49, for measuring glucose (sugar) in whole capillary blood. The Unistrip1™ is meant for self-testing of blood glucose as an aid to monitor the effectiveness of diabetes control.

They are for single patient use only and should not be shared.

They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, palm, or forearm.

Testing is done outside the body (in vitro diagnostic use).

They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control.

Not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

UniStrip1™ Test Strips allow alternate site testing (AST) from the fingertip, palm and/or the forearm. (Use of palm AST is not to be done with OneTouch® Ultra® meter). Alternative site testing should only be done during steady-state times (when glucose is not changing rapidly).
Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).

Predicate Product Comparison
Similarities to Predicate Device

Characteristic	Predicate Device	New Device
Reagent Composition	Glucose Oxidase (Aspergillus niger)	Same as predicate
Specimen Type	Fresh capillary whole blood	Same as predicate
Sample Volume	1.0 µL	Same as predicate
Control Solution	Use OneTouch® Ultra® Control Solution	Use Prodigy® Control Solution
Detecting Range	20-600 mg/dL	Same as predicate
Calibration	Various codes	Code 49 Only
Altitude Use	Up to 10,000 feet	Same as predicate
Storage Temperature	Less than 86°F (30° C)	39°-86°F (4°-30°C)
Open Vial Shelf Life	6 months after opening	90 days after opening

Differences with Predicate Device

Characteristic	Predicate Device	New Device
Control Solution	Use OneTouch® Ultra® Control Solution	Use Prodigy® Control Solution
Calibration	Various codes	Code 49 Only
Storage Temperature	Less than 86°F (30° C)	39°-86°F (4°-30°C)
Open Vial Shelf Life	6 months after opening	90 days after opening

Safety and Effectiveness Tests and Studies Non-Clinical
The following tests and studies were conducted to ensure the UniStrip1™ Test Strips were safe and effective when using the UniStrip1™ Test Strip with the following blood glucose meters - OneTouch®Ultra®, OneTouch®Ultra2®, OneTouch® UltraMini® and One-Touch® UltraSmart®.

- NCCLS EP5-A Precision Test
- NCCLS EP6-A Linearity Test
- ISO 15971 Hematocrit Test
- ISO 15971 and EP7-A2 Interference Tests
- ISO 15971 System Accuracy Evaluation
- ISO 15971 and ISO 5725-1 Comparison Test
- ISO 15971 Altitude Test
- Volume Verification Study
- EN 13640 Operation Conditions Tests for Test Strip
- EN 13640 Storage Conditions Test for Test Strip
- ISO 15971 Control Solution test

ISO 159712 and ISO 5725-1 User Evaluation

- Error Code Comparison Tests

Clinical Studies

No clinical studies were conducted.

Conclusion

Based on the Predicate Product Comparison Table of similarities, standard and FDA guidance tests and study results UniStrip Technologies, LLC concludes that no new issues of safety and effective have been raised in this original 510(k) submission for the UniStrip1™ Test Strips to be used with the OneTouch®Ultra®, OneTouch®Ultra2®, OneTouch® UltraMini® and One-Touch® UltraSmart® blood glucose meters purchased before October 2012.

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

November 6, 2013

UniStrip Technologies, LLC
Richard Admani
Chief Operations Officer
2701-A Hutchison McDonald Rd.
CHARLOTTE, NC 28269

Re: K113135
Trade/Device Name: UniStrip 1 Test Strip
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: November 01, 2013
Received: November 04, 2013

Dear Mr. Admani:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Carol C. Benson -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

Indications for Use

510(k) Number (if known): K113135

Device Name: UniStrip1 Test Strip

Indications for Use:

The Unistrip1 Test Strips are used with the OneTouch® Ultra®, OneTouch®Ultra2®, OneTouch® UltraMini® and One-Touch® UltraSmart® meters purchased before October 2012, set at calibration code 49, for measuring glucose (sugar) in whole capillary blood. The Unistrip1 is meant for self-testing of blood glucose as an aid to monitor the effectiveness of diabetes control.

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Stayce Beck

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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