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

OK BIOTECH CO., LTD.
DR. KE-MIN JEN
OFFICIAL CORRESPONDENT
NO. 91, SEC. 2, GONGDAO 5TH ROAD
HSINCHU CITY 30070
TAIWAN

July 29, 2016

Re: K160038
Trade/Device Name: UniStrip1 Generic Blood Glucose Test Strips
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: June 3, 2016
Received: June 14, 2016

Dear Dr. KeMin Jen:

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)*
K160038

Device Name
UniStrip1 Generic Blood Glucose Test Strips

Indications for Use *(Describe)*
The UniStrip1™ Generic Blood Glucose Test Strips are used with the OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before April 2016, and OneTouch® Ultra® purchased before October 2012, set at calibration code 49, for measuring glucose (sugar) in whole capillary blood. The strips are 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.
The UniStrip1™ Generic Blood Glucose 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).
The UniStrip™ Control Solutions are for use with the UniStrip1™ Generic Blood Glucose Test Strips and OneTouch® Ultra® meters to check that the meters and test strip 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

5. 510(k) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

Type Of 510(K) Submission	Traditional
Basis for the submission	Additional or Expanded Indications
Common Name Of The Proposed Device	BLOOD GLUCOSE TEST STRIPS
Trade name	UniStrip1 Generic Blood Glucose Test Strips
510(k) Submitter	OK BIOTECH CO., LTD. No. 91, Sec. 2, Gongdao 5th Road, 30070, Hsinchu City, Taiwan Telephone: +886-3-516-0258 Fax:+886-3-516-0028 Email: service@okbiotech.com
Owner Number	9090860
Date prepared	July 29, 2016
Official Correspondent	Dr. JEN, KE-MIN TEL: 886-3-5208829 FAX: 886-3-5209783 Email: ceirs.jen@msa.hinet.net
Preference For Continued Confidentiality (21 CFR 807.95)	510(k) Summary
Device Classification Name	System, Test, Blood Glucose, Over The Counter
Regulation Description	Glucose test system
Review Panel	Clinical Chemistry
Product Code	NBW, CGA, JJX
Regulation number	21 CFR 862.1345
Class	2
Primary Predicate Device	UniStrip Technologies, LLC UniStrip1™ Test Strips K113135
Secondary Predicate Device (for control solution)	DIAGNOSTIC DEVICES, INC PRODIGY BLOOD GLUCOSE TEST SYSTEM K060467

- **Intended Use:**

The UniStrip1™ Generic Blood Glucose Test Strips are used with the OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before April 2016, and OneTouch® Ultra® purchased before October 2012, set at calibration code 49, for measuring glucose (sugar) in whole capillary blood. The strips are 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.
The UniStrip1™ Generic Blood Glucose 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).
The UniStrip™ Control Solutions are for use with the UniStrip1™ Generic Blood Glucose Test Strips and OneTouch® Ultra® meters to check that the meters and test strip are working together properly and that the test is performing correctly.

- **Device Description:**

UniStrip1 Generic Blood Glucose Test Strips are used with the OneTouch® Ultra, OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters. The test strips are intended for use outside the body (in vitro diagnostic use) by people with diabetes using the OneTouch® Ultra®, OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® blood glucose monitoring systems as an aid to monitor the effectiveness of diabetes control. UniStrip1 Generic Blood Glucose 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). UniStrip1 Generic Blood Glucose Test Strips can only be used with the OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before April 2016, and OneTouch® Ultra® purchased before October 2012. UniStrip1 Generic Blood Glucose Test Strips are only for use with calibration code 49.

- **Test Principle**

The OneTouch® Ultra® Family Meters are plasma-calibrated to allow easy comparison of results with laboratory methods. Glucose in the blood sample mixes with special chemicals on the UniStrip1 Generic Blood Glucose Test Strips and a small electrical current is produced. This current is measured by the OneTouch® Ultra® Family Meters and displayed as your blood glucose result. The strength of the current changes with the amount of glucose in the blood sample.

- **Comparison Table**

Item	Predicate device	Subject device
Manufacturer	UniStrip Technologies, LLC	OK Biotech Co., Ltd.
Device trade name	UniStrip1™ Test Strips	UniStrip1 Generic Blood Glucose Test Strips
510(k) number	K113135	K160038
Common name	Blood Glucose Test Strips	Blood Glucose Test Strips
Classification name	System, Test, Blood Glucose, Over The Counter	System, Test, Blood Glucose, Over The Counter
Regulation Description	Glucose, Oxidase, Glucose	Glucose, Oxidase, Glucose
Product code	NBW, CGA	NBW, CGA, JJX
Regulation number	21 CFR 862.1345	21 CFR 862.1345
Device class	II	II
Review panel	Clinical Chemistry	Clinical Chemistry
Similarities		
Test Principle	The OneTouch® Ultra® Family Meters are plasma-calibrated to allow easy comparison of results with laboratory methods. Glucose in the blood sample mixes with special chemicals on the UniStrip1 Test Strips and a small	Same test principle

	electrical current is produced. This current is measured by the OneTouch® Ultra® Family Meters and displayed as your blood glucose result. The strength of the current changes with the amount of glucose in the blood sample.	
Enzyme	Glucose oxidase (Aspergillus niger)	Same enzyme
Specimen Type	Capillary whole blood from fingertip and alternative sites palm, forearm. (Use of palm AST is not to be done with OneTouch® Ultra® meter).	Same specimen type
Sample Volume	1.0 μL	Same sample volume
Operating Temperature	42 - 111 °F (6 - 44 °C) 10 - 90% R.H.	Same operating temperature
HCT Range	30 - 55%	Same HCT range
Calibration	Code 49 only	Same calibration code
Detecting Limit	20 - 600 mg/dL	Same detecting limit
Measuring time	5 seconds	Same measuring time
Open vial shelf life	90 days after opening	Same open vial shelf life
Chemical makeup of test strips	1. Glucose oxidase (Aspergillus niger): 20 lU 2. Potassium ferricyanide: 0.12 mg 3. Non-reactive ingredients: 1.8 mg	Same chemical makeup of test strips
Chemical makeup of control solution	**510(k) cleared as K060467** 1. D-Glucose 2. Polyvinyl acetate (aqueous emulsion): 10% 3. Antifoaming agent (Polyethylene Glycol 4000): 0.02% 4. Disodium EDTA: 0.1% 5. Fumed silica: 0.2% 6. Food Pigment Red No.6: 0.05% 7. Sodium Benzoate: 0.2%	**Same chemical makeup of control solution as K060467**

Differences:		
Item	Predicate device	Subject device
Indications for use	The UniStrip1 Test Strips are used with the OneTouch® Ultra®, OneTouch® Ultra®2, 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 (AST) should only be done during steady-state times (when glucose is not changing rapidly).	The UniStrip1™ Generic Blood Glucose Test Strips are used with the OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before April 2016, and OneTouch® Ultra® purchased before October 2012, set at calibration code 49, for measuring glucose (sugar) in whole capillary blood. The strips are 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. The UniStrip1™ Generic Blood Glucose 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). The UniStrip™ Control Solutions are for use with the UniStrip1™ Generic Blood Glucose Test Strips and OneTouch® Ultra® meters to check that the meters and test strip are working together properly and that the test is performing correctly.

Strip Storage Temperature	39 °F – 86 °F (4 °C – 30 °C)	39 °F – 104 °F (4 °C – 40 °C)
Brand name of Control solution	Prodigy Control Solution (K060467)	UniStrip Control Solution (same as K060467)

- **Safety and Effectiveness Tests and Non-Clinical Studies**

The following tests and studies were conducted to ensure the UniStrip1 Generic Blood Glucose Test Strips used with the following blood glucose meters: OneTouch® Ultra®2, OneTouch® UltraMini® and One-Touch® UltraSmart® meters purchased before April 2016, and OneTouch® Ultra® purchased before October 2012 were safe and effective in measuring blood glucose concentration.

1. **Sample volume study** per ISO 15197:2013 In vitro diagnostic test systems — Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

   As the test results shown, the glucose measurements of sample volume from 1.0 to 1.5 μL met acceptance criteria. The sample volume of the System was required at least 1.0 μL to obtain the normal testing results.

2. **Operation condition study** per EN 23640:2013 In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents

   The performance of the UniStrip1 Generic Blood Glucose Test Strips with OneTouch Series Blood Glucose Meters was evaluated in the normal and extreme environments. According to the test results, the individual bias was within ±10 mg/dL at glucose concentration < 75 mg/dL and within ±10 % at glucose concentration ≥ 75 mg/dL. The SD was less than 5.0 mg/dL at glucose concentration < 75 mg/dL, and the CV was less than 5.0 % at glucose concentration ≥ 75 mg/dL. The test results met the acceptance criteria. Therefore, UniStrip1 Generic Blood Glucose Test Strips and UniStrip Control Solution were operated normally in the conditions 42 -111 ^{0}F (6 – 44 °C), 10 – 90% R.H.

3. **Hematocrit Study** per ISO 15197:2013 In vitro diagnostic test systems — Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

   According to the study data, when blood sample with HCT from 30 % to 55 %, (1) all of SD and CV were less than 5 mg/dL and 5% in this study, respectively, (2) All of the individual bias of glucose measurement compared with YSI mean was less than 15%, (3) the Mean Bias% to YSI for each sample of blood glucose concentration at each hematocrit level was less than 10%, and (4) The Difference % between the mean glucose bias and the mean bias of the mid-level sample (Hct: 42%) was less than 10%. The test results met the acceptance criteria. In summary, the HCT ranges from 30% to 55% were available for UniStrip1 Generic Blood Glucose Test Strips used with OneTouch Ultra series meters including Ultra2, UltraMini and UltraSmart purchased before April 2016.

4. **Altitude study** per ISO 15197:2013 In vitro diagnostic test systems — Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

   The study shows the individual bias fall within ± 10 % at the altitude from 298 feet (91 meters) to 11,161 feet (3,402 meters). The SD at blood glucose concentration < 75 mg/dL and CV at the blood glucose concentration ≥ 75 mg/dL for the measurements were less than 5.0 mg/dL and 5.0 %, respectively. The results meet the acceptance criteria. So it shows no significant effects on the UniStrip1 Generic Blood Glucose Test Strips with OneTouch Series Blood Glucose Meters including OneTouch Ultra2, UltraMini and UltraSmart at various altitudes from 298 feet to 11,161 feet (91 to 3,402 meters). Thus we claim the UniStrip1 Generic Blood Glucose Test Strips with OneTouch Ultra series meters including OneTouch Ultra2, OneTouch UltraMini and OneTouch UltraSmart purchased before April 2016 can be used up to 10,000 ft

5. **Linearity study** per NCCLS/CLSI EP6-A:2014 Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (FDA recognition number 7-193)

   According to the test results shown in the following table, the correlation coefficient R^2 is greater than 0.95. That is to say, our test results were highly

correlated with YSI 2300. The linearity is available from 20 to 600 mg/dL. 100 % of the bias of individual glucose results fallen within ± 10 mg/dL at glucose concentration < 75 mg/dL, and within ±10% at glucose concentration ≥ 75 mg/dL compared with Glucose Analyzer YSI 2300. The test results met the acceptance criteria. So the UniStrip1 Generic Blood Glucose Test Strips used with the One Touch Ultra2, One Touch UltraMini and OneTouch UltraSmart purchased before April 2016 pass the linearity study.

Linear regression analysis:

Meter	Test Site	Linearity	R^2
One Touch® Ultra 2®	Fingertip	Y=0.9783X + 1.4938	0.9829
	Palm	Y=0.9718X + 2.3621	0.9876
	Forearm	Y=0.9945X - 0.891	0.9865
One Touch® UltraMini®	Fingertip	Y=0.9759X + 1.686	0.9849
	Palm	Y=0.9928X - 0.7268	0.9848
	Forearm	Y=0.9773X + 1.299	0.9856
One Touch® UltraSmart®	Fingertip	Y=0.9806X + 1.3315	0.9853
	Palm	Y=0.9924X - 0.8447	0.9849
	Forearm	Y=1.0152X - 2.6014	0.9884

6. **Precision study** per NCCLS/CLSI EP05-A3:2015 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline- Third Edition (FDA recognition number 7-251)

   According to the test results, the pooled and maximum SD were less than 5.0 mg/dL at glucose concentration < 75 mg/dL, and pooled and maximum CV were less than 5.0 % at glucose concentration ≥ 75 mg/dL. The maximum individual bias was less than 10 % compared with glucose analyzer YSI 2300. The test results met the acceptance criteria. The UniStrip1 Generic Blood Glucose Test Strips used with the OneTouch Ultra series meters, including OneTouch Ultra2, OneTouch UltraMini and OneTouch UltraSmart. purchased before April 2016, pass the repeatability evaluation and intermediate precision evaluation.

Within Run

Repeatability		Lot I					Lot II					Lot III				
OneTouch® Ultra®2	Mean (mg/dL)	42.0	79.2	128.9	199.0	324.8	41.8	78.9	129.0	199.1	324.5	41.7	79.0	128.3	198.8	322.6
	SD	1.4	1.4	2.6	3.6	7.2	1.5	1.4	2.6	3.9	6.1	1.5	1.5	2.7	4.3	7.2
	CV	3.3%	1.8%	2.0%	1.8%	2.2%	3.5%	1.8%	2.0%	2.0%	1.9%	3.5%	1.9%	2.1%	2.2%	2.2%
	n	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50
OneTouch® UltraMini®	Mean (mg/dL)	41.7	79.1	128.4	198.7	326.3	42.3	79.2	129.4	198.4	325.6	41.9	78.9	129.3	199.1	322.2
	SD	1.4	1.5	2.5	4.6	8.2	1.4	1.5	2.7	4.3	9.3	1.4	1.3	2.8	4.4	8.8
	CV	3.2%	1.9%	1.9	2.3%	2.5%	3.3%	1.9%	2.1%	2.2%	2.9%	3.4%	1.7%	2.2%	2.2%	2.7%
	n	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50
OneTouch® UltraSmart®	Mean (mg/dL)	42.5	79.0	129.2	199.0	324.1	42.0	78.8	129.1	198.3	325.5	41.6	79.5	130.0	199.0	325.6
	SD	1.3	1.2	2.8	4.5	6.5	1.4	1.1	2.7	4.4	7.9	1.4	1.4	2.6	4.0	7.6
	CV (%)	3.1%	1.5%	2.2%	2.3%	2.0%	3.2%	1.5%	2.1%	2.2%	2.4%	3.4%	1.8%	2.0%	2.0%	2.3%
	n	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50

Between Run

Intermediate Precision	Lot I			Lot II			Lot III		
Mean (mg/dL)	39.0	118.9	260.5	39.0	119.2	259.7	39.0	119.0	260.3
SD	0.8	3.2	8.0	0.8	3.1	7.7	0.8	3.3	8.0
CV	2.1%	2.7%	3.1%	2.1%	2.6%	3.0%	2.1%	2.8%	3.1%

7. **Interference study** per ISO 15197:2013 In vitro diagnostic test systems — Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus and NCCLS/CLSI EP07-A2:2007 Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (FDA recognition number 7-127)

   According to the data, all bias of test results within the range listed above were less than 10% compared with the measurements of the controlled pool. Based on the testing results, the concentration limits of all the interfering substances were higher than therapeutic or physiological levels. That is to say, no obvious interference was observed in the interfering substance at neither therapeutic nor physiological levels at two blood glucose levels.

8. **Error message verification study**

9. **Shelf-Life study** per EN 23640:2013 In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents and ISO 15197:2013 in vitro diagnostic test systems — Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

   According to the test results, all of the data met the acceptance criteria. The closed vials of the UniStrip1 Generic Blood Glucose Test Strips are stable for 24 months and 90 days for in-use vials. The closed and in-use vials of UniStrip Control Solutions were stable for 18 months and 90 days respectively.

10. **User Performance Evaluation** per ISO 15197:2013 In vitro diagnostic test systems — Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus and ISO 15725-1:2011 Accuracy (trueness and precision) of measurement methods and results — Part 1: Introduction and basic principles

According to the evaluation results, after a certain period of manual reading, the blood glucose monitoring systems can be operated properly by a lay user for finger and alternative site testing (the palm and forearm). The test results show that the populations of individual bias ± 15 mg/dL at blood glucose concentration < 75 mg/dL and ± 15 % at blood glucose concentration ≥ 75 mg/dL compared with Glucose Analyzer YSI 2300 are more than 95 %. The test results met the acceptance criteria. That is, the blood glucose monitoring system could be operated properly by lay users. That is, UniSrtip1 Generic Blood Glucose Test Strips with OneTouch Ultra series meters purchased before April 2016, including OneTouch Ultra2, OneTouch UltraMini and One-Touch UltraSmart meters could be operated properly by lay users.

11. Satisfactory Evaluation

More than 85 % of volunteers agree that the labels on the packing and the users' guide provided enough information of the product for the readers. More than 95 % of volunteers' score were higher than 80 points. It indicates that the written materials could provide enough information of the product for the lay users, so they can comprehend the contents easily even without the instructions given by professional.

12. MSDS for D-Glucose in UniStrip Control Solutions

13. MSDS for Glucose Oxidase in UniStrip1 Generic Blood Glucose Test Strips

14. **MSDS for PET in UniStrip1 Generic Blood Glucose Test Strips**

- **Substantial Equivalence (SE) Discussion**

A claim of substantial equivalence is made to *UniStrip1 Test Strips (K113135)* made by *UniStrip Technologies, LLC.* Both of them have the similar indications for use, the same working principle and technologies including using the same chemical makeup of test strips and control solution, the same sample volume, same measuring time, same operating temperature, same HCT range, same open vial shelf life, same calibration code, and detecting range.

The major differences for two devices are the **extended valid period** between October 2012 and April 2016 of the subject device used with OneTouch® Ultra®2, OneTouch® UltraMini® and One-Touch® UltraSmart® meters, **strip storage temperature** and **brand name** of control solution. The subject device covers **2.5 more years of valid period** than the predicate device. The **more 18 Fahrenheit degrees in strip storage temperature range** than the predicate device has been validated and verified by the relevant testing to show the expected performance of blood glucose measuring for the subject device. The UniStrip Control Solutions are made up of the same chemical makeup as the predicate Prodigy Control Solution. Refer to the attached "Transfer and Assignment of 510(K) Ownership and Registrations 2012-24-12". These differences will not pose any change in the safety and effectiveness. Besides, the subject device and predicate device are same intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger, and the following alternative sites: the palm and the forearm. The differences will not raise any safety and effectiveness concerns. They are substantially equivalent.

- **Synopsis of Test Methods and Results**

Pre-clinical data are employed upon submission of this 510(k) premarket notification according to the FDA Guidance Document: Review Criteria of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology. 02/28/1997.

- **Conclusion**

Based on the comparison table, the comparison discussion, complying standards and FDA guidance, we concludes that no new issues of safety and effectiveness have been raised in this original 510(k) submission for the UniStrip1 Generic Blood Glucose Test Strips used with the OneTouch® Ultra®2, OneTouch® UltraMini® and One-Touch® UltraSmart® meters purchased before April 2016, and OneTouch® Ultra® purchased before October 2012.