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

January 19, 2017

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

Re: K162430
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
Dated: December 6, 2016
Received: December 15, 2016

Dear Ke-Min 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)*

K162430

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®, OneTouch®, Ultra®2, OneTouch®, UltraMini® and OneTouch®, UltraSmart® meters purchased before April 2016, 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).

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)*

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

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## 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.<br>No. 91, Sec. 2, Gongdao 5th Road, 30070,<br>Hsinchu City, Taiwan<br>Telephone: +886-3-516-0258<br>Fax:+886-3-516-0028<br>Email: service@okbiotech.com |
| Date prepared | December 6, 2016 |
| Official Correspondent | Dr. Jen, Ke-min<br>TEL: +886-3-5208829 FAX: +886-3-5209783<br>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 |
| Regulation number | *21 CFR 862.1345* |
| Class | *2* |
| Predicate Device | OK Biotech Co., ltd.<br>*UniStrip1™ Generic Blood Glucose Test Strips*<br>*K160038* |

- **Indications for Use:**

The UniStrip1™ Generic Blood Glucose Test Strips are used with the OneTouch® Ultra®, OneTouch Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before April 2016, 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 alternative site testing (AST) from the fingertip, palm and/or the forearm. (Use of palm AST is not to be done with OneTouch® Ultra® meter). Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).

- **Device Description:**

The UniStripl Generic Blood Glucose Test Strips are used with the OneTouch® Ultra, OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters. The UniStrip1 Generic Blood Glucose 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. 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). The UniStrip1 Generic Blood Glucose Test Strips can only be used with the OneTouch® Ultra®, OneTouch Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before April 2016. UniStripl 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** |
|---|---|---|
| **Trade name** | UniStrip1 Generic Blood Glucose Test Strips | UniStrip1 Generic Blood Glucose Test Strips |
| **Manufacturer** | OK Biotech Co., Ltd. | OK Biotech Co., Ltd. |
| **510(k) No.** | K160038 | K162430 |
| **Similarities** | | |
| **Test Principle** | Glucose in the blood sample mixes with glucose oxidase on the UniStrip1 test strip and a small electrical current is measured by the meter(s) and displayed as your blood glucose results. The strength of this current changes with the amounts of glucose in the blood sample. | Same |
| **Enzyme** | Glucose oxidase (*Aspergillus niger*) | Same |
| **Specimen Type** | Capillary whole blood from fingertip and alternate sites (palm, forearm and upper-arm)<br>(Use of palm AST is not to be done with OneTouch® Ultra® meter). | Same |
| **Sample Volume** | 1.0 μL | Same |

| | | |
|---|---|---|
| **Operating Temperature** | 43 – 111 $^{0}$F (6 - 44 $^{o}$C )<br>10 - 90% R.H. | Same |
| **HCT Range** | 30 - 55% | Same |
| **Detecting Limit** | 20 - 600 mg/dL | Same |
| **Measuring time** | 5 seconds | Same |
| **Strip Storage Temperature** | 39 – 104 $^{o}$F (4 – 40 °C) | Same |
| **Opened test strips vial shelf life** | 90 days after first opening | Same |
| **Unopened test strips vial shelf life** | 24 months | Same |
| **Brand name of Control solution** | UniStrip Control Solutions | Same |
| **Ingredient Chemicals of the UniStrip1 Generic Blood Glucose Test Strips** | 1. Glucose oxidase (Aspergillus niger): 20 lU<br>2. Potassium ferricyanide: 0.12 mg<br>3. Non-reactive ingredients: 1.8 mg | Same |
| **Ingredient Chemicals of the Control Solutions** | 1. D-Glucose<br>2. Polyvinyl acetate (aqueous emulsion): 10%<br>3. Antifoaming agent (Polyethylene Glycol 4000): 0.02%<br>4. Disodium EDTA: 0.1%<br>5. Fumed silica: 0.2%<br>6. Food Pigment Red No.6: 0.05%<br>7. Sodium Benzoate: 0.2% | Same |
| **Differences** | | |
| **Indications for Use** | The UniStrip1™ Generic Blood Glucose Test Strips are used with the OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmar$^{t®}$ meters purchased **before April 2016**, and OneTouch® | The UniStrip1™ Generic Blood Glucose Test Strips are used with the OneTouch® Ultra®, OneTouch Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased **before April** |

| | | |
|---|---|---|
| | 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.<br>They are for single patient use only and should not be shared.<br>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).<br>They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control.<br>Not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.<br>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).<br>Alternative site testing should only be done during steady-state times (when glucose is not changing rapidly). | **2016**, 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.<br>They are for single patient use only and should not be shared.<br>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).<br>They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control.<br>Not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.<br>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). |

- **Substantial Equivalence Discussions**

A claim of substantial equivalence is made to *UniStrip1 Generic Blood Glucose Test Strips (K160038)* made by OK Biotech Co., Ltd. Both devices actually are identical ones, except for the differences of valid dates for the OneTouch® Ultra® meters purchased before April 2012 and purchased before April 2016. This 4-year extra valid period for the OneTouch® Ultra® meter has been validated by conducting the performance testing on the OneTouch® Ultra® meters, The difference of validated dates for the OneTouch® Ultra® meters will not raise any safety or effectiveness concerns. They are substantially equivalent.

- **Summary of Performance Tests and Non-Clinical Studies**

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

1. **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 Standard Deviations (SD) at blood glucose concentration < 100 mg/dL and CV at the blood glucose concentration ≥ 100 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® Ultra® Meters at various altitudes from 298 feet to 11,161 feet (91 to 3,402 meters). We claim that it can be used up to 10,000 ft.*

2. **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 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%. Also, (3) The Mean Bias% to YSI for each sample of blood glucose concentration at each hematocrit level was less than 10%. (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 with OneTouch® Ultra® Meters.*

3. **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 per **NCCLS/CLSI EP07-A2:2007** Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (FDA recognition number 7-127)

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

4. **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 our test results, the correlation coefficient is greater than 0.95. That is, 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 fall within ± 10 mg/dL at glucose concentration < 100 mg/dL, and 10% at glucose concentration ≥ 100 mg/dL compared with Glucose Analyzer YSI 2300. The test results shown in the following table met the acceptance criteria*

| Strips lots | Slope | Intercept | $R^2$ | r |
|---|---|---|---|---|
| Lot I | 0.994 | -1.0434 | 0.9988 | 0.9994 |
| Lot II | 1.0037 | 0.6514 | 0.9985 | 0.99925 |
| Lot III | 1.0039 | 0.389 | 0.9991 | 0.99955 |

5. **Operation condition study**

*The performance of the UniStrip1 Generic Blood Glucose Test Strips with OneTouch® Ultra® 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 < 100 mg/dL and within ±10 % at glucose concentration ≥ 100 mg/dL. The SD was less than 5.0 mg/dL at glucose concentration < 100 mg/dL, and the CV was less than 5.0 % at glucose concentration ≥ 100 mg/dL. The test results met the acceptance criteria. Therefore, UniStrip1 Generic Blood Glucose Test Strips used with the OneTouch® Ultra® Blood Glucose Meters and UniStrip Control Solutions were operated normally in the conditions 42- 111 $^{0}$F (6~44 $^{o}$C), 10 – 90% R.H.*

6. **Precision study** per **NCCLS/CLSI EP05-A3:2015** Evaluation of Precision of Quantitative Measurement Procedures, Approved Guideline-Third Edition (In Vitro Diagnostics) (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 were less than 10 % compared with glucose analyzer YSI 2300. The test results shown in the following tables met the acceptance criteria*

| Level | Level I | Level II | Level III | Level IV | Level V |
|---|---|---|---|---|---|
| YSI 2300 | 43.3 | 79.6 | 129 | 201 | 325 |
| Mean | 43.0 | 79.1 | 129 | 201.4 | 324.6 |
| Max Bias | -5.3% | -3.3% | 3.1% | 3.5% | 3.7% |
| Max CV | 3.7% | 2.0% | 2.4% | 2.3% | 2.6% |
| Pooled CV | 3.3% | 1.8% | 2.0% | 2.1% | 2.2% |

| Repeatability | Lot I | | | | | Lot II | | | | | Lot III | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mean (mg/dL) | 42.9 | 79.1 | 129.2 | 201.5 | 325.6 | 43.0 | 79.0 | 128.8 | 201.3 | 324.2 | 42.9 | 79.1 | 129.0 | 201.3 | 324.2 |
| SD | 1.4 | 1.5 | 2.8 | 4.1 | 6.8 | 1.4 | 1.5 | 2.7 | 4.2 | 7.8 | 1.5 | 1.4 | 2.5 | 4.7 | 6.8 |
| CV | 3.2% | 1.8% | 2.1% | 2.0% | 2.1% | 3.2% | 1.9% | 2.1% | 2.1% | 2.4% | 3.5% | 1.8% | 1.9% | 2.3% | 2.1% |
| n | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

| Intermediate Precision | Lot I | | | Lot II | | | Lot III | | |
|---|---|---|---|---|---|---|---|---|---|
| Mean (mg/dL) | 39.1 | 119.2 | 258.1 | 39.0 | 118.5 | 256.6 | 39.0 | 119.2 | 257.6 |
| SD | 1.4 | 4.6 | 9.6 | 1.4 | 4.6 | 9.5 | 1.4 | 4.6 | 10.0 |
| CV | 3.6% | 3.8% | 3.7% | 3.6% | 3.9% | 3.7% | 3.6% | 3.9% | 3.9% |

7. **Shelf-Life study** per **EN 23640:2013** In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents

   *According to the test results, all of the data met the acceptance criteria. That is, the unopened vials of the UniStrip1 Generic Blood Glucose Test Strips were stable for **24 months** and **90 days** for opened vials.*

8. **User performance (Lay users) evaluation**

   *After a certain period of independent reading, the blood glucose monitoring systems can be operated properly by a lay user for fingertips and alternate site testing (the forearm). All of correlation values $R^2$ were greater than 0.98, and it meant glucose measurements of the UniStrip1 Generic Blood Glucose Test Strips with the OneTouch® Ultra® Meters were highly correlated to the measurements of Glucose Analyzer YSI 2300. 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.*

**Measurements performed by lay users for Lot I versus YSI 2300**

For glucose concentration < 75 mg/dL

| Test site | Within ±5 mg/dL | Within ±10 mg/dL | Within ±15 mg/dL |
|---|---|---|---|
| Fingertip | 13/20 (65.0%) | 17/20 (85.0%) | 20/20 (100.0%) |
| Forearm | 13/20 (65.0%) | 18/20 (90.0%) | 20/20 (100.0%) |

For glucose concentration ≥ 75 mg/dL

| Test site | Within ±5% | Within ±10% | Within ±15% | Within ±20% |
|---|---|---|---|---|
| Fingertip | 52/80 (65.0%) | 71/80 (88.8%) | 80/80 (100.0%) | 80/80 (100.0%) |
| Forearm | 50/80 (62.5%) | 73/80 (91.3%) | 80/80 (100.0%) | 80/80 (100.0%) |

**Linearity analysis results for fingertip test**

| Strip lots | Linearity equation | $R^2$ |
|---|---|---|
| Lot I | $Y$=0.9982$X$+1.2235 | 0.9827 |
| Lot II | $Y$=0.9658$X$+3.4959 | 0.9816 |
| Lot III | $Y$=1.0132$X$-2.2274 | 0.9876 |

**9. Satisfactory evaluation**

*More than 85 % of volunteers agreed that the labels on the packing and the users' guide provided enough information of the product for the readers. More than 95 % of volunteers' scores 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 explanation by professional.*

**10. Sample volume study**

*As the test results show the glucose measurements of sample volume are from 1.0 to 1.5 μL. The sample volume of UniStrip1 Generic Blood Glucose Test Strips with OneTouch® Ultra® Meters was required at least 1.0 μL to obtain the normal testing results.*

**11. Error message verification study**

According to our test results, the error messages of OneTouch® Ultra® Meters displayed correctly at the given condition of procedures. The test results of UniStrip1 Generic Blood Glucose Test Strips met the acceptance criteria.

12. **MSDS for Glucose Oxidase** in UniStrip1 Generic Blood Glucose Test Strips

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

- **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.

- **Conclusions**

Based on the comparison table, substantial equivalence discussion, and FDA guidance document, OK Biotech 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®, OneTouch® Ultra®2, OneTouch® UltraMini® and One-Touch® UltraSmart® meters purchased before April 2016.