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

Re: K141914
Trade/Device Name: Prodigy® Autocode Eject TM Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: March 1, 2015
Received: March 11, 2015

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,

Stayce Beck -S

For: Courtney H. Lias, Ph.D.
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

PRODIGY® AutoCode Eject TM Blood Glucose Monitoring System

Indications for Use (Describe)
Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy® AutoCode® Eject 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. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

PRODIGY® No Coding Test Strips are intended for use with the PRODIGY® AutoCode® Eject blood glucose meter to measure the concentration of the blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only). Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY® No Coding Test Strips are used as an aid to monitor the effectiveness of diabetes control.

This system contains a speaking function, but is not intended for use by the visually impaired.

Type of Use (Select one or both, as applicable)

- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [x] 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: A New Device
Common Name Of The Proposed Device: Blood Glucose Monitoring System
Trade name: PRODIGY AutoCode Eject™ Blood Glucose Monitoring System

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: April 14, 2015
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
Classification Regulation: SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER
(21 CFR 862.1345)
Class: II
Panel: Clinical Chemistry
Product Code: NBW
Predicate Device: PRODIGY Preferred® Blood Glucose Monitoring System (K122338)

Intended Use:

Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy® AutoCode® Eject 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. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System should not be used for the diagnosis of,
or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

PRODIGY® No Coding Test Strips are intended for use with the PRODIGY® AutoCode® Eject blood glucose meter to measure concentration of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only). Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY® No Coding Test Strips are used as an aid to monitor the effectiveness of diabetes control.

This system contains a speaking function, but is not intended for use by the visually impaired.

**Device Description:**

The Prodigy® AutoCode® Eject Blood Glucose Monitoring System consists of a meter and Prodigy No Coding Test Strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.


The Prodigy No Coding Test Strips utilizes the active enzyme is Glucose Oxidase, derived from Aspergillus niger. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System has a speaking function.

**Test Principle**

The Blood glucose test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.
### Comparison Table

<table>
<thead>
<tr>
<th>Comparison Items</th>
<th>Subject device</th>
<th>Predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANUFACTURER</td>
<td>OK Biotech Co., Ltd.</td>
<td>Prodigy Diabetes Care, LLC</td>
</tr>
<tr>
<td>BRAND NAME</td>
<td>Prodigy</td>
<td>Prodigy</td>
</tr>
<tr>
<td>Model Number</td>
<td>AutoCode Eject™</td>
<td>Preferred®</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Prodigy® AutoCode Eject™ Blood Glucose Monitoring System</td>
<td>Prodigy Preferred® Blood Glucose Monitoring System</td>
</tr>
<tr>
<td>Product Code</td>
<td>NBW</td>
<td>NBW</td>
</tr>
<tr>
<td>510K NO</td>
<td>K141914</td>
<td>K122338</td>
</tr>
</tbody>
</table>

### Similarities

| Indications for use | Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred |
| Test Principle | The test is based on the measurement of electrical

| Same |
Current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.

<table>
<thead>
<tr>
<th>Enzyme</th>
<th>Glucose oxidase</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Type</td>
<td>Capillary whole blood from fingertip and alternative sites (palm, forearm, upper-arm, calf and thigh)</td>
<td>Same</td>
</tr>
<tr>
<td>Test Strip</td>
<td>PRODIGY® No-Coding Test Strips</td>
<td>Same</td>
</tr>
<tr>
<td>Control solution</td>
<td>PRODIGY® Control Solution (Level 1 &amp; Level 2)</td>
<td>Same</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>0.7 µL</td>
<td>Same</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>50 ºF - 104 ºF 10~85% R. H.</td>
<td>Same</td>
</tr>
<tr>
<td>Strip Storage Temperature</td>
<td>39.2 - 104 ºF 10~85% R. H.</td>
<td>Same</td>
</tr>
<tr>
<td>HCT Range</td>
<td>20 ~ 60 %</td>
<td>Same</td>
</tr>
<tr>
<td>Detecting range</td>
<td>20~600 mg/dL</td>
<td>same</td>
</tr>
<tr>
<td>code-checking mechanism</td>
<td>Code number checking</td>
<td>Same</td>
</tr>
<tr>
<td>temperature compensation mechanism</td>
<td>Automatic compensation with built-in thermistor</td>
<td>Same</td>
</tr>
</tbody>
</table>

**Differences**

<table>
<thead>
<tr>
<th>Measuring Time</th>
<th>6 seconds</th>
<th>7 seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meter size</td>
<td>100 mm (L) × 56 mm (W) × 23</td>
<td>71 mm (L) × 60 mm (W) × 19</td>
</tr>
<tr>
<td></td>
<td>mm (H)</td>
<td>mm (H)</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Meter Weight</td>
<td>Approximate 79 g (w/battery)</td>
<td>Approximate 45 g (w/battery)</td>
</tr>
<tr>
<td>Power Battery</td>
<td>1.5V AAA Alkaline battery x2</td>
<td>One 3V CR2032 battery</td>
</tr>
<tr>
<td>Memory Storage</td>
<td>450 tests</td>
<td>120 tests</td>
</tr>
<tr>
<td>Speaking feature</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

- **Substantial Equivalence (SE) Discussion**
  
  A claim of substantial equivalence is made to PRODIGY Preferred® Blood Glucose Monitoring System (K122338). Both of them have the same indications for use, the same working principle and technologies including using the same Prodigy No-Coding test strips and PRODIGY Control Solution, sample volume, operating & storage conditions, HCT range, detecting range.
  
  The major differences for the two devices are measuring time, meter dimensions, meter weight; power battery, memory storage, and speaking feature. The speaking function for the subject device is indicated not to be used by visually impaired person, just an aid for all of the users. The subject device and predicate device are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. Thus the differences are due to the feature design aspects, not related to the safety or effectiveness aspects. They are substantially equivalent.

- **Synopsis of Test Methods and Results**
  
  Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA document provided by CDRH/ FDA.

- **Conclusion**
  
  The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.