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

July 20, 2016

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

Re: K152599
Trade/Device Name: PRODIGY Astro Blood Glucose Monitoring System,
PRODIGY Astro PRO Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: July 1, 2016
Received: July 08, 2016

Dear Dr. Jen, Ke-Min

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)*
K152599

Device Name
PRODIGY Astro Blood Glucose Monitoring System

Indications for Use *(Describe)*
Prodigy® Astro 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® Astro Blood Glucose Monitoring System is intended to be used in the home by a single person and should not be shared. The Prodigy® Astro 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® Astro 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 Astro blood glucose meters 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.

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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FOR FDA USE ONLY

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

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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:

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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)*
K152599

Device Name
PRODIGY Astro PRO Blood Glucose Monitoring System

Indications for Use *(Describe)*
Prodigy® Astro PRO 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® Astro PRO Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use by healthcare professionals in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The Prodigy® Astro PRO 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 PRO No Coding Test Strips are intended for use with the PRODIGY Astro PRO blood glucose meters to measure concentration of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The system should only be used with single-use, auto-disabling lancing devices.

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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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 Astro Blood Glucose Monitoring System* *PRODIGY Astro PRO 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	July 1, 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
Classification Regulation	SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER (21 CFR 862.1345)
Class	II
Panel	Clinical Chemistry
Product Code	CGA, NBW
Predicate Device	*PRODIGY AutoCode Eject Blood Glucose Monitoring System* **(K141914)**

- **Intended Use:**

Prodigy Astro Blood Glucose Monitoring System

Prodigy® Astro 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® Astro Blood Glucose Monitoring System is intended to be used in the home by a single person and should not be shared. The Prodigy® Astro 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® Astro 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 Astro blood glucose meters 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.

Prodigy Astro PRO Blood Glucose Monitoring System

Prodigy® Astro PRO 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® Astro PRO Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use by healthcare professionals in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The Prodigy® Astro PRO 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 PRO No Coding Test Strips are intended for use with the PRODIGY Astro PRO blood glucose meters to measure concentration of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The system should only be used with single-use, auto-disabling lancing devices.

Device Description:

The Prodigy Astro Blood Glucose Monitoring System and the Prodigy Astro PRO Blood Glucose Monitoring System are identical devices (hereafter both are called the System), but the latter is claimed to be used not only in the home by a single person but also in professional healthcare settings.

The System consists of a meter and Prodigy No Coding Test Strips (or Prodigy PRO 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 System is marketed as a meter only with a carrying case, batteries, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card. The System is also marketed as a meter kit with a carrying case, batteries, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card, Prodigy Lancing Device, Prodigy Lancets, Prodigy No Coding Test Strips, and Control Solution.

The Prodigy No Coding Test Strips utilizes the active enzyme, Glucose Oxidase, derived from Aspergillus niger.

- **Test Principle**

Electrochemical biosensor with carbon electrodes that is referring to detection of glucose by the test strips. The 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**

Comparison Items	Predicate device	Subject device
MANUFACTURER	OK Biotech Co., Ltd.	OK Biotech Co., Ltd.
BRAND NAME	Prodigy	Prodigy
Model Number	AutoCode Eject	Astro
Trade Name	Prodigy® AutoCode EjectTM Blood Glucose Monitoring System	*Prodigy® AstroTM Blood Glucose Monitoring System *Prodigy® AstroTM PRO Blood Glucose Monitoring System
Product Code	CGA, NBW	CGA, NBW
510(k) No.	K141914	K152599
Similarities		
Test Principle	Electrochemical biosensor with carbon electrodes that is referring to detection of glucose by the test strips. The 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.	Same principle
Enzyme	Glucose oxidase	Same Enzyme
Specimen Type	Capillary whole blood from fingertip and alternative sites (palm, forearm, upper-arm, calf and thigh)	Same specimen type
Test Strip	PRODIGY® No Coding Test Strips	*PRODIGY No Coding Test Strips *PRODIGY PRO No Coding Test Strips Same as K141914

Control solution	PRODIGY® Control Solution (Level 1 & Level 2)	Same control solution as K141914
Sample Volume	0.7 µL	Same sample volume
Operating Conditions	50 °F - 104 °F 10~85% RH. (non-condensing)	Same Operating Conditions
Strip Storage Conditions	39 °F - 104 °F 10~85% R.H. (non-condensing)	Same Strip Storage Conditions
HCT Range	20 ~ 60 %	Same HCT range
Detecting range	20~600 mg/dL	Same detecting range
Temperature compensation mechanism	Automatic compensation with built-in thermistor	Same mechanism
Measuring Time	6 seconds	Same measuring time
Memory Storage	450 tests	Same memory storage
Power Battery	1.5V AAA Alkaline battery x2	Same power batteries
Differences		
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 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	*Indications for use of the Prodigy Astro Blood Glucose Monitoring System are the same as the predicate device except for the speaking function. *The IFU of Prodigy Astro PRO Blood Glucose Monitoring System is almost the same as the predicate device, and the major difference is that it is intended to be used in professional healthcare settings and has no speaking function.

	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.	
Meter size	100 mm (L) × 56 mm (W) × 23 mm (H)	108.5 mm (L) × 62.5 mm (W) × 30 mm (H)
Meter Weight	Approximate 79 g (with batteries)	Approximate 105 g (with batteries)
Speaking feature	Yes	No

- **Substantial Equivalence (SE) Discussion**

  A claim of substantial equivalence is made to PRODIGY AutoCode Eject Blood Glucose Monitoring System (K141914). Both of them have the same working principle and technologies, including using the same Prodigy No-Coding Test Strips (or Prodigy PRO No Coding Test Strips).and PRODIGY Control Solution.

  The major differences for the two devices are intended use, meter dimensions, meter weight, speaking feature. The speaking function for the predicate device is indicated not to be used by visually impaired person, just an aid for all of the users. The subject device, Prodigy Astro BGMS, is indicated for use in the home by a single-person and should not be shared, and Prodigy Astro PRO GMS in professional healthcare settings. The predicate device is intended for use only in the home by a single-person. The subject device thus differentiates the users by providing two separate sets of Owner's Manuals, product labels and Boxes labels. The other differences, meter weight and size, are due to the feature design aspects, not related to the safety and effectiveness concerns.

- **Summary of the Non-Clinical Performance Characteristics**

The following non-clinical testing was conducted on the *PRODIGY Astro Blood Glucose Monitoring System (BGMS)* to show substantial equivalence to the predicate device:

- Software verification and validation testing (IEC 62304:2006, FDA Guidance, 5/2005)
- Electromagnetic Compatibility Study (IEC 60601-1-2:2007: Electromagnetic Compatibility, IEC 61326-1:2012, IEC 61326-2-6:2005, Emission: CISPR 11:2009 +A1:2010, Class B, Immunity: IEC 61000-4-2:2008, IEC 61000-4-3:2010, IEC 61000-4-8:2009
- Electrical Safety testing (IEC 60601-1: 2005, IEC 61010-1:2010, IEC 61010-2-101:2002, FCC 47 CFR Part 15 Subpart B/Oct. 2013 and CISPR 22/1997 (Class B Limit)
- Robustness Evaluation (FDA Guidance, Jan/2014)
- Precision Evaluation (FDA Guidance 02/28/1997, NCCLS EP5-A2)
- Linearity Evaluation (NCCLS/CLSI, EP6-A, FDA Guidance 02/28/1997,
- System Accuracy Evaluation (FDA Guidance 02/28/1997)
- Hematocrit Evaluation (FDA Guidance 02/28/1997)
- Interference Study (FDA Guidance 02/28/1997, CLSI EP7-A2)
- Operation Condition Study (EN 13640)
- Sample Volume Study
- Virucide Evaluation for Case & Lens materials (CLSI EP17-A)
- Altitude Study (FDA Guidance 02/28/1997)
- Mechanical Resistance Study (IEC 60068-2-64:1993, IEC 61010-1:2010)
- Shelf Life Study of Test Strips
- Shelf Life Study of the Meters

Testing demonstrated the *PRODIGY Astro (or Astro PRO) BGMS (abbreviated as **the Systems**)* meets all relevant standards requirements. Internal verification and validation testing confirm that the product specifications are met which are equivalent in design and technological characteristics to the predicate device. Testing of the *Systems* supports the claims of substantial equivalence to the predicate device.

Software validation: All software documentation was prepared and submitted for the device in accordance with FDA guidance documents. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Device Hazard Analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes.

Electrical safety: The Systems complies with the applicable voluntary standards for the Electrical Safety. The device passed all the electrical safety testing according to national & international standards including IEC 60601-1: 2005, IEC 61010-1:2010, IEC 61010-2-101:2002, FCC 47 CFR Part 15 Subpart B/Oct. 2013 and CISPR 22/1997 (Class B Limit).

Electromagnetic Compatibility The Systems have been tested and successfully met all of the relevant sections (Radiated Emissions, Electrostatic Discharge Immunity Test, Radiated Radio-Frequency Electromagnetic Immunity, and Power Frequency Magnetic Field Immunity Test to complies to all standards including IEC 60601-1-2:2007: Electromagnetic Compatibility, IEC 61326-1:2012, IEC 61326-2-6:2005, Emission: CISPR 11:2009 +A1:2010, Class B, Immunity: IEC 61000-4-2:2008, IEC 61000-4-3:2010, IEC 61000-4-8:2009.

Robustness Study: The Systems are intended for single-patient use or for use in professional healthcare settings. According to the study results with the use of PDI SUPER SANI-CLOTH germicidal disposable wipes (EPA Reg. No. 9480-4), the deterioration of all of the components of the devices did not occur and the devices were operated correctly after cleaning and disinfection treatments. The number of cleaning and disinfection cycles validated for the Prodigy Astro BGMS and for the Prodigy Astro Pro BGMS are 520 and 10950 cycles respectively. The individual bias of the meter measurements compared with individual YSI mean were less than 10 mg/dL at glucose concentrations < 75 mg/dL and less than ± 10 % at glucose concentrations ≥ 75 mg/dL. The test results met acceptance criteria.

Precision Evaluation: The Systems were evaluated in accordance with FDA Guidance 02/28/1997, NCCLS EP5-A User Evaluation of Precision Performance of Clinical Chemistry Devices. The subject device within-run and between-run tests over the blood glucose concentration range of 20-600 mg/dL and Control Levels 1 and 2 showed the pooled and maximum SD were less than 5.0 mg/dL at glucose concentration < 100 mg/dL, and pooled and maximum CV were less than 5.0 % at glucose concentration ≥ 100 mg/dL. The maximum individual bias was less than 10 % compared with glucose analyzer YSI 2300. The test results met the acceptance criteria. The subject devices pass the Precision Evaluation.

Linearity Evaluation: The Systems were tested to determine the linearity in accordance with CLSI document EP6-A, “Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach”. The Systems were shown to demonstrate high linearity over the range 10.46 mg/dL to 672.9 mg/dL. The claimed blood glucose measuring range is 20 to 600 mg/dL, same as the predicate device. Linear regression showed the correlation coefficient is greater than 0.95, as shown in the following Table. That is, our test results were highly correlated with YSI 2300. The

linearity of our measurement is acceptable between 20 to 600 mg/dL. 100 % of the bias or bias (%) of individual glucose results fallen within ±10 % or 10%. The test results met the acceptance criteria. The subject devices pass the Linearity Evaluation.

Table: The separate regression analysis for each lot of test strips

Lot	Slope	Intercept	R^2	r
I	0.9993	1.2852	0.9998	0.9998
II	1.0054	-1.352	0.9996	0.9997
III	0.9942	0.5085	0.9999	0.9999
All	0.9996	0.1473	0.9999	0.9999

System Accuracy Evaluation: The Systems were evaluated for system accuracy using YSI as the reference standard. According to the internal test results, more than 95% of tests results fall within ±15 mg/dL at blood glucose concentration < 75 mg/dL, and within ±15 % at glucose concentration ≥75 mg/dL. A study result evaluating blood glucose values drawn from fingertip, palm, forearm, upper arm, calf, and thigh capillary blood samples obtained by 100 lay persons, tested with 3 lots of test strips, was shown in the Table below. The test results met the acceptance criteria. The subject devices pass the System Accuracy Evaluation.

Table – System accuracy evaluation results

For glucose concentrations < 75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	11/15 (73.3%) 10/15 (66.7%) 11/15 (73.3%)	14/15 (93.3%) 13/15 (86.7%) 14/15 (93.3%)	15/15 (100%) 15//15 (100%) 15/15 (100%)
Palm	13/15 (86.7%) 10/15 (66.7%) 12/15 (80%)	14/15 (93.3%) 15/15 (100%) 15/15 (100%)	15/15 (100%) 15/15 (100%) 15/15 (100%)
Forearm	11/15 (73.3%) 9/15 (66.7%) 9/15 (66.7%)	14/15 (93.3%) 14/15 (93.3%) 15/15 (100%)	15/15 (100%) 15/15 (100%) 15/15 (100%)
Upper arm	11/15 (73.3%) 9/15 (60%) 10/15 (66.7%)	14/15 (93.3%) 14/15 (93.3%) 14/15 (93.3%)	15/15 (100%) 15//15 (100%) 15/15 (100%)
Calf	10/15 (66.7%) 9/15 (60%) 10/15 (66.7%)	14/15 (93.3%) 15/15 (100%) 15/15 (100%)	15/15 (100%) 15//15 (100%) 15/15 (100%)
Thigh	11/15 (73.3%) 11/15 (73.3%) 10/15 (66.7%)	14/15 (93.3%) 14/15 (93.3%) 14/15 (93.3%)	15/15 (100%) 15//15 (100%) 15/15 (100%)

For glucose concentrations ≥ 75 mg/dL

Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
Finger	64/85 (75.3%) 51/85 (60%) 54/85 (63.5%)	80/85 (94.1%) 71/85 (83.57%) 76/85 (89.4%)	85/85 (100%) 84/85 (98.8%) 84/85 (98.8%)	85/85 (100%) 85/85 (100%) 85/85 (100%)
Palm	54/85 (63.5%) 52/85 (61.2%) 50/85 (58.8%)	72/85 (94.7%) 73/85 (85.9%) 76/85 (89.4%)	83/85 (97.6%) 84/85 (98.8%) 84/85 (98.8%)	85/85 (100%) 85/85 (100%) 85/85 (100%)
Forearm	57/85 (65.9%) 53/85 (62.4%) 53/85 (62.4%)	78/85 (91.8%) 75/85 (88.2%) 74/85 (87.1%)	83/85 (97.6%) 82/85 (96.5%) 82/85 (96.5%)	85/85 (100%) 85/85 (100%) 85/85 (100%)
Upper arm	57/85 (67.1%) 52/85 (61.2%) 55/85 (64.7)	77/85 (90.65%) 76/85 (89.4%) 77/85 (90.6%)	84/85 (98.8%) 84/85 (98.8%) 83/85 (97.6%)	85/85 (100%) 85/85 (100%) 85/85 (100%)
Calf	57/85 (67.1%) 51/85 (60%) 52/85 (61.2)	79/85 (92.9%) 78/85 (91.8%) 74/85 (87.1%)	84/85 (98.8%) 83/85 (97.65%) 81/85 (95.3%)	85/85 (100%) 85/85 (100%) 85/85 (100%)
Thigh	57/85 (67.1%) 51/85 (60%) 52/85 (61.2)	82/85 (96.5%) 72/85 (84.7%) 80/85 (94.1%)	84/85 (98.8%) 82/85 (96.5%) 84/85 (98.8%)	85/85 (100%) 85/85 (100%) 85/85 (100%)

Hematocrit Evaluation: The effect of varying hematocrit (HCT) levels on the performance of the Prodigy Astro Blood Glucose Monitoring System was evaluated over an HCT range of 20-60%. All of the individual difference of the blood glucose measurements compared with individual YSI mean fall within ±10% from HCT 20% to 60%. Also, all of the individual bias of the BGM measurements compared with the mean of BGM measurements in HCT 42% fall within ±10 % from HCT 20 % to HCT 60 %. All of SD and CV were within 5.0 mg/dL and 5.0% in this study, respectively. The test results met the acceptance criteria. In summary, the HCT ranges from 20% to 60% were available for the Systems.

Interference Study: The interference study was completed per CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition. Interference studies were performed on the Systems. 7 endogenous and 19 exogenous interfering substances were evaluated by spiking venous blood to three levels of glucose concentrations (50-100, 200-275, 400-500 mg/dL). The glucose samples were then spiked with the potentially interfering compounds. Five meters and three lots of test strips were used for this study. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. The bias of mean test results within the range listed above were ≤ 10% compared with the YSI mean measurements. 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 three blood glucose levels. A summary of the maximum concentrations of the potential interfering substances tested is summarized in the table below:

Table -- A summary of the maximum concentrations of the potential interfering

substances tested

Chemicals	Max Concentration
1. Acetaminophen	≤ 8.0 mg/dL
2. Ascorbic acid	≤ 5.0 mg/dL
3. Aspirin	≤ 60 mg/dL
4. Bilirubin	≤ 90 mg/dL
5. Cholesterol	≤ 500 mg/dL
6. Creatinine	≤ 5.0 mg/dL
7. Dopamine	≤ 2.0 mg/dL
8. EDTA	≤360 mg/dL
9. Galactose	≤ 900 mg/dL
10. Gentisic acid	≤ 5.0 mg/dL
11. Glutathione	≤53 mg/dL
12. Haemoglobin	≤500 mg/dL
13. Heparin	≤8000 U/dL
14. Hydroxyurea	≤ 3.0 mg/dL
15.Ibuprofen	≤50 mg/dL
16. Icodextrin	≤13 mg/dL
17. L-dopa	≤ 10 mg/dL
18. Maltose	≤ 900 mg/dL
19. Methyldopa	≤ 3.0 mg/dL
20. Pralidoxime Iodide	≤25 mg/dL
21. Salicylate	≤60 mg/dL
22. Tolazamide	≤50 mg/dL
23. Tolbutamide	≤ 400 mg/dL
24. Triglyceride	≤ 2000 mg/dL
25. Uric acid	≤ 8.0 mg/dL
26. Xylose	≤100 mg/dL

Operation Condition Study: The performance of the test strips was evaluated in the normal and extreme environments. According to the test results, the individual bias was less than ± 10 % and CV/SD were less than 5.0 % and 5.0 mg/dL. The test results met the acceptance criteria**.** This study confirmed the operation conditions of the Systems for the temperature range of 50-104 ^{o}F, and the humidity range of 10~85% R.H. (non-condensing).

Sample Volume Study: Based on the data evaluation, the test values of volumes between 0.7 and 1.5 μL fall within acceptable criteria. In order to obtain more accurate results, testing blood glucose value with the Systems is required at least 0.7 μL of blood sample.

Virucide Evaluation for Case & Lens materials: The study indicated that PDI SUPER SANI-CLOTH germicidal disposable wipes (EPA Reg. No. 9480-4) within 2 minutes contact time can completely inactivate the Hepatitis B Virus at undiluted (HBsAg: 7857.9 IU/mL), 10X, 100X and 1000X virus dilution on the Case & Lens coupons.

Altitude Study: The study shows the individual results fall within ± 10 % at the altitude from 298 feet (91 meters) to 11,161 feet (3,402 meters). The results met the acceptance criteria. So it shows no significant effects on the Systems at the altitudes from 298 feet to 11,161 feet (91 to 3,402 meters)..

Mechanical Resistance Study: The Systems were examined to test the operational limits of the system and to validate the insensitivity of the system to performance variation under stress conditions. Accordingly, the following tests were carried out:

1) **Vibration test:** Ten Astro meters were subjected respectively to vibration tester for 30 min for X axis, 30 min for Y axis and 30 min for Z axis, then doing the blood glucose measurement with 3 lots of test strips.
2) **Drop test**: Ten Astro meters are released respectively from 1 meter high above a horizontal hardwood, then doing the blood glucose measurement with 3 lots of test strips.

All studies showed the meters could stand the vibration and drop testing required in IEC 60068-2-64:1993 and IEC 61010-1: 2010.

Shelf Life Study of Test Strips: According to the test result, all the data met the acceptance criteria. That is, the unused test strips were stable for 25 months and 96 days for opened vials. We can claim the shelf-life of PRODIGY No Coding Test Strip is 24 months for unopened strips vials and 90 days for opened strips vials.

Shelf Life study of the meter: The meter can be used for 5 years at the test frequency

twice a day and all functions were normal after 5 years and 4000 tests.

- **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 devices are substantially equivalent to the predicate devices.