K122340

# 510(k) Summary

**807.92(c)**

**SPONSOR** **807.92(a)(1)**

| | |
|---|---|
| Company Name: | Prodigy Diabetes LLC |
| Company Address: | 9300 Harris Corners Parkway<br>Suite 450<br>Charlotte, NC 28269 |
| Telephone: | 704-285-6400 |
| Fax: | 704-285-6475 |
| Contact Person: | Rick Admani |
| Summary Preparation Date: | October 24, 2013 |

NOV 2 6 2013

**DEVICE NAME** **807.92(a)(2)**

| | |
|---|---|
| Trade Name: | Prodigy® Choice Blood Glucose Monitoring System |
| Common/Usual Name: | Blood Glucose Meter |
| Classification Name: | System, Test, Blood Glucose, Over the Counter |
| Regulation Number: | 862.1345 |
| Product Code: | NBW, CGA |
| Device Class: | II |
| Panel: | Clinical Chemistry |

**PREDICATE DEVICE** **807.92(a)(3)**

Legally Marketed Equivalent Device

| *Company* | *Product* | *510(k) #* |
|---|---|---|
| Diagnostic Devices, Inc. | Prodigy Voice BGMS | K073118 |

**DEVICE DESCRIPTION** **807.92(a)(4)**

The Prodigy Choice Blood Glucose Monitoring System consists of a meter and 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 Choice Blood Glucose Monitoring System is marketed as a meter only with a carrying case, battery, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card. The Prodigy Choice Blood Glucose Monitoring System is also marketed as a meter kit with a

carrying case, battery, 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 utilize the enzyme glucose oxidase, which is derived from recombinant protein derived from the fungus *Aspergillus niger*.

**DEVICE INTENDED USE** **807.92(a)(5)**

The Prodigy Choice 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, palm, upper-arm, calf or thigh. The Prodigy Choice Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Prodigy Choice 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 Choice Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Prodigy Choice Test Strips are for use with the Prodigy Choice Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, palm, upper-arm, calf or thigh.

**COMPARISON OF TECHNICAL CHARACTERISTICS** **807.92(a)(6)**

Prodigy Choice Blood Glucose Monitoring System has equivalent technological characteristics and intended use as the Prodigy Voice Blood Glucose Monitoring System (K073118). The Choice Blood Glucose Monitoring System does not have the Voice capability.

**PERFORMANCE TESTING** **807.92(b)**

Prodigy Choice Blood Glucose Monitoring System was tested to the required standards for blood glucose monitoring systems including:

ISO 15197
NCCLS EP9-A
NCCLS SP5-A
ISO 14971

Prodigy Choices Blood Glucose Monitoring System was also tested for label comprehension and usability with a Human Factor Study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

PRODIGY DIABETES CARE, LLC
c/o E.J. SMITH
SMITH ASSOCIATES
1468 HARWELL AVENUE
CROFTON MD 21114

Re: K122340
Trade/Device Name: Prodigy Choice Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: October 21, 2013
Received: October 21, 2013

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K122340

Device Name
Prodigy Choice Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Prodigy Choice 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, palm, upper-arm, calf or thigh. The Prodigy Choice Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Prodigy Choice 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 Choice Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Prodigy Choice Test Strips are for use with the Prodigy Choice Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, palm, upper-arm, calf or thigh.

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)*

Stayce Beck