510(k) Summary

SPONSOR
Company Name: Prodigy Diabetes LLC

Company Address: 9300 Harris Corners Parkway
Suite 450
Charlotte, NC 28269

Telephone: 704-285-6400
Fax: 704-285-6475
Contact Person: Rick Admani

Summary Preparation Date: October 24, 2013

DEVICE NAME
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
Legally Marketed Equivalent Device

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

DEVICE DESCRIPTION

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.
PRODIGH 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” (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 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 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
Proody Choice Blood Glucose Monitoring System

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

Concurrently at Center for Devices and Radiological Health (CDRH) (Signature)

Stayce Beck

FORM FDA 3221 (8/13)