K103115

OCT 12 2011

510(k) Summary
807.92(c)

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

Company Name:	Prodigy Diabetes LLC
Company Address:	9300 Harris Corners Parkway Suite 450 Charlotte, NC 28269
Telephone:	704-285-6400
Fax:	Fax: 704-285-6475
Contact Person:	Rick Admani

Summary Preparation Date: October 14, 2010

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

Trade Name:	Prodigy® Diabetes Management Software
Common/Usual Name:	Blood Glucose Meter and Data Management
Classification Name:	System, Test, Blood Glucose, Over the Counter
Regulation Number:	862.1345
Product Code:	NBW;JQP
Device Class:	II
Panel:	Clinical Chemistry

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

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Becton Dickinson	BD™ Diabetes Software	K023219

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

The Prodigy® Diabetes Management Software is a moderate level of concern software management system that allows the user an additional method of tracking their blood glucose level. The software allows for data transfer from a Prodigy Blood Glucose Monitor via a USB cable. The Prodigy® Diabetes Management Software is designed to operate on the patient's PC with Microsoft SQL Server 2005 or later operating system. Prodigy® Diabetes Care LLC website will provide a link to download the Microsoft SQL Server 2005.

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

The Prodigy® Diabetes Management Software is indicated for use as a data management tool for the acceptance, transfer, display, storage, processing (e.g., averaging). Reporting, and printing of patient blood glucose monitoring data.

The Prodigy® Diabetes Management Software is indicated for use with the Prodigy Blood Glucose Monitoring Systems only.

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

Parameters	Prodigy Diabetes Management Software	Becton Dickinson Diabetes Software
510(k) Number:		K023219
Indications for Use	The Prodigy® Diabetes Management Software is indicated for use as a data management tool for the acceptance, transfer, display, storage, processing (e.g., averaging). Reporting, and printing of patient blood glucose monitoring data. The Prodigy® Diabetes Management Software is indicated for use with the Prodigy Blood Glucose Monitoring Systems only.	The BD™ Diabetes Software is intended for use as a data management tool for acceptance, transfer, display, storage, processing (e.g. averaging), reporting, and printing for patient blood glucose monitoring data. The device is intended for use with the BD Blood Glucose Monitoring Systems only.
Download blood glucose meter readings via USB interface cable	Yes	Yes
Electronic Log Book	Yes	Yes
Create User Profile	Yes	Yes
Create reports		
Create trending graphs	Yes	Yes
Option for printing reports	Yes.	Yes
Features of the Software System		
Set Target – target blood glucose range	Yes	Yes
Average reading for each meal over the past several	Yes	Yes

weeks		
Over –the-Counter	Yes	Yes

SUBSTATIAL EQUIVALENCE

The software feature comparisons above of the BD™ Diabetes Software and the Prodigy® Diabetes Management Software demonstrate that the Prodigy® software system is substantially equivalent to the predicate device based on the following similarities:

- Patient can create personal and meter profiles
- Patient can import data from the Prodigy Blood Glucose Meter,
- Patient can set blood glucose target ranges and personal schedule,
- Patient has a Log book to view recorded data,
- Patient can retrieve reports and trending graphs, and
- Patient can print Trend graphs and reports

PERFORMANCE DATA

A clinical usability study was performed to verify ease of use and label comprehension.

CONCLUSION **807.92(b)(3)**

Based on the product comparison and the Human Factor Study Prodigy® Diabetes Care LLC concludes that the Prodigy® Diabetes Management Software does not raise any new issues concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Prodigy Diabetes Care, LLC.
c/o Smith Associates
E.J. Smith, Consultant
1468 Harwell Avenue,
Crofton, MD 21114

OCT 12 2011

Re: k103115
Trade/Device Name: Prodigy Diabetes Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name:Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: September 28, 2011
Received: September 28, 2011

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103115

Device Name: Prodigy® Diabetes Management Software

Indications for Use:

The Prodigy® Diabetes Management Software is intended for use as a data management tool for acceptance, transfer, display, storage, processing (e.g. averaging), reporting and printing of patient blood glucose monitoring data.

The device is intended for use with the Prodigy® Blood Glucose Monitoring Systems only.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 103115