510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:
k103115

B. Purpose for Submission:
New 510(k) for diabetes data management software accessory for use with compatible cleared Prodigy (k060467) and Prodigy Voice (k073118) Blood Glucose Meter.

C. Manufacturer and Instrument Name:
Prodigy Diabetes Care, LLC. Prodigy Diabetes Management Software

D. Type of Test or Tests performed:
Diabetes data management system

E. System Descriptions:

1. Device Description:
   The Prodigy® Diabetes Management Software 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.

2. Principles of Operation:
   Prodigy Diabetes Management Software is an accessory to compatible Prodigy meters, which use specific test principles.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

   Yes __X__ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

   Yes _____ or No _ X___

4. Specimen Identification:
   Meter controlled download to data manager

5. Specimen Sampling and Handling:
   Not Applicable

6. Calibration:
   Not Applicable

7. Quality Control:
   Not Applicable

8. Software:

   FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes__X___ or No _____

F. Regulatory Information:

1. Regulation Section:
   21CFR §862.1345 -Glucose test system.
   21CFR §862.2100 - Calculator/data processing module for clinical use.

2. Classification:
   Class II and I respectively

3. Product Code:
   NBW - System, Test, Blood Glucose, Over the Counter
   JQP - Calculator/Data Processing Module, for Clinical Use

4. Panel:
   Chemistry (75)

G. Intended Use:

1. Indication(s) 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.

2. Special Condition for use Statement(s):
   Over the Counter (OTC) use

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:

Becton Dickinson, BD™ Diabetes Software
k023219

2. Comparison with Predicate Device:

Parameters	Prodigy Diabetes Management Software	Becton Dickinson Diabetes Software
510(k) Number:	k103115	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.	Same
Compatibility	for use with the Prodigy Blood Glucose Monitoring Systems only.	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 weeks	Yes	Yes
Over the Counter	Yes	Yes

I. Standard/Guidance Document Referenced (if applicable):

ISO 14971:2007, Medical Devices – Application of risk management to medical devices

J. Performance Characteristics:

1. Analytical Performance:
    - *a. Accuracy:*
      Not Applicable
    - *b. Precision/Reproducibility:*
      Not Applicable
    - *c. Linearity:*
      Not Applicable
    - *d. Carryover:*
      Not Applicable
    - *e. Interfering Substances:*
      Not Applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

   A Human Factors study of 20 participants was performed to verify ease of use, label comprehension meter data transfer in the hands of lay users. Additionally, all meters were bench tested to verify data transfer compatibly and accuracy utilizing full memory capacity.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.