K040603

MAY 19 2004

510K Summary of Safety and Effectiveness

1. **Submitted By:**

John Schalago
Manager, Regulatory Affairs

BD Medical
Diabetes Care
1 Becton Drive
Franklin Lakes, NJ 07417-1883
Phone: 201-847-5663
Fax: 201-848-0457

2. **Device Name:**

Trade Name: BD Paradigm Link™ Blood Glucose Monitor

Common Names: Glucose oxidase, glucose test system

Classification Name: Glucose oxidase, glucose test system

3. **Predicate Device:**

Paradigm Link – K030531

BD Logic™ Blood Glucose Monitor

Medtronic MiniMed ComLink™

4. **Device Description:**

The BD Paradigm Link™ Blood Glucose Monitor is an *in-vitro* diagnostic device for use in the quantitative measurement of glucose in capillary blood collected from fingertips. The BD Paradigm Link™ is designed to be simple and easy to use. It provides accurate blood glucose test results in 5 second while requiring a very small (0.3 µL) sample.

The BD Paradigm Link™ is also designed for wireless communication with Medtronic MiniMed External Insulin Pumps (511 and higher). When used with Medtronic MiniMed 512 External Insulin Pump, blood glucose test values obtained using the BD Paradigm Link™ can be automatically transmitted to the insulin pump for use in the Bolus Wizard feature of the Medtronic MiniMed 512 External Insulin Pump. Consumers or healthcare practitioners may also use the meter as a communication device to facilitate transfer of information between the pump and a personal computer.

510K Summary of Safety and Effectiveness *(Continued)*

5. **Intended Use:**

The BD Paradigm Link™ Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The BD Paradigm Link™ Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip

When used with a MiniMed Pump, the BD Paradigm Link Blood Glucose Monitor can automatically telemeter glucose values to the Model 512 Insulin Pump using radio frequency communication. The BD Paradigm Link Blood Glucose Monitor can also serve as a radio frequency interface to allow communication between the MiniMed insulin pump and a personal computer running the appropriate Medtronic MiniMed communications software.

6. **Technological Characteristics:**

The BD Paradigm Logic™ Blood Glucose Monitor is based on biosensor (glucose oxidase) technology. When blood is applied to the BD Test Strip, reagents on the strip react with the blood and a current is generated. The Paradigm Link™ employs amperometric technology to measure the glucose concentration in the blood sample by measuring the amount of current that is generated and flows through the electrodes on the test strip.

The BD Paradigm Link™ is designed for wireless communication using radio-frequency (RF) technology. The RF telemetry functionality of the Paradigm Link™ allows the meter to automatically telemeter glucose values to a MiniMed pump or to be used as a radio frequency interface to allow communication between a MiniMed insulin pump and a personal computer.

7. **Performance Summary:**

Laboratory and Human Factors studies demonstrate that the BD Paradigm Link™ performed in an equivalent manner to the predicate devices and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 9 2004

Mr. John A. Schalago MS, RAC
Regulatory Affairs Manager
Becton Dickinson & CO.
BD Consumer Healthcare
1 Becton Drive
Franklin Lakes, NJ 07417-1885

Re: k040603
Trade/Device Name: BD Paradigm Link™ Blood Glucose Monitor
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: March 04, 2004
Received: March 30, 2004

Dear Mr. Schalago:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040603

Device Name: BD Paradigm Link™ Blood Glucose Monitor

Indications For Use:

The BD Paradigm Link Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The BD Paradigm Link Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.

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

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

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

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040603