K041478

OCT 2 8 2004

510(K) SUMMARY

1. **Submitted By:**

John Schalago
Manager, Regulatory Affairs

BD Medical - Diabetes Care
1 Becton Drive
Franklin Lakes, NJ 07417-1883

Phone: 201-847-5663
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2. **Device Name:**

Trade Name:	BD Logic™ Blood Glucose Monitor Paradigm Link™ Blood Glucose Monitor
Common Names:	Glucose oxidase, glucose test system
Classification Name:	Glucose oxidase, glucose test system

3. **Predicate Devices:**

BD Logic™ Blood Glucose Monitor
Paradigm Link™ Blood Glucose Monitor
Bayer Glucometer Dex®
TheraSense FreeStyle®

4. **Device Description:**

BD Logic and Paradigm Link Blood Glucose Monitors are intended for use in the quantitative measurement of glucose in capillary blood collected from the fingertip, palm and forearm.

BD Logic and Paradigm Link Blood Glucose Monitors are designed to be simple and easy to use. The monitors provide accurate blood glucose test results in 5 seconds using a small (0.3 µL) sample volume. The lancing device is available with a standard adjustable depth setting lancet cap and an off-finger lancet cap with a set lancing depth.

510(K) SUMMARY (*Continued*)

5. **Intended Use:**

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

The BD Logic and Paradigm Link Blood Glucose Monitors are specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm or forearm.

6. **Technological Characteristics:**

BD Logic and Paradigm Link Blood Glucose Monitoring Systems work by using biosensor technology. When blood is applied to the Blood Glucose Test Strip, reagents on the test strip react with the blood and a current is generated. BD Logic and Paradigm Link Blood Glucose Monitoring Systems employ amperometric technology to measure the glucose concentrations in the blood sample by measuring the amount of current that is generated and flows through the electrodes on the test strip.

7. **Performance Summary:**

Clinical studies were conducted to evaluate the use of BD Logic and Paradigm Link Blood Glucose Monitors for alternate anatomical site testing during steady state and periods of dynamic glycemic change. The results demonstrate that BD Logic and Paradigm Link Blood Glucose Monitoring Systems are suitable for fingertip, palm or forearm testing when performed in accordance with the device labeling. In addition, clinical study data demonstrate that during period of rapid glucose change, testing on the palm is equivalent to fingertip testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John A. Schalago MSBME, RAC
Regulatory Affairs Manager
Becton Dickinson
BD Medical-Diabetes Care
1 Becton Drive
Franklin Lakes, NJ 07417

OCT 2 8 2004

Re: k041478
Trade/Device Name: BD Logic™ and Paradigm Link™ Blood Glucose Monitoring Systems
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: October 12, 2004
Received: October 13, 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

Indications for Use

510(k) Number (if known):_____

Device Name: BD Logic™ and Paradigm Link™ Blood Glucose Monitoring Systems

Indications For Use:

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

BD Logic™ and Paradigm Link ™Blood Glucose Monitors are specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm, and forearm.

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)

Division Sign-Off

Page 1 of 1

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041478