K983344

JUN 2 2 1999

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Dade Behring QuikLYTE™ MetaboLYTE Cartridge

FDA Classification Name: Glucose Test System and Urea Nitrogen Test System

The Dade Behring QuikLYTE™ MetaboLYTE cartridge performs two *in vitro* diagnostic tests: glucose (GLU7) and urea nitrogen (BUN7).

> Intended Use: The GLU7 and BUN7 methods on the QuikLYTE™ Module of the Dimension®XL/RxL clinical chemistry system are in vitro diagnostic tests intended for the quantitative measurement of glucose in serum, plasma and cerebrospinal fluid and of urea nitrogen in serum and plasma using Integrated Multisensor Technology (IMT).

The glucose (GLU7) and urea nitrogen (BUN7) methods use a sample which is diluted automatically on-board the Dimension® XL or RxL clinical chemistry system. The diluted sample is then processed in a multisensor cartridge that uses Integrated Multisensor Technology (IMT). The glucose method uses amperometric detection and the urea nitrogen method uses potentiometric detection to measure the specific analyte in the sample.

The assays performed by the Dade Behring QuikLYTE™ MetaboLYTE cartridge are substantially equivalent to the glucose (GLU) and urea nitrogen (BUN) methods packaged in FLEX™ reagent cartridges, which were cleared by the FDA through the 510(k) process. Both methodologies are processed on an automated system, the Dimension® clinical chemistry system, and are used for the determination of glucose in human serum, plasma, and cerebrospinal fluid and urea nitrogen in human serum or plasma.

A split sample comparison study was conducted with the following results:

	Slope	Intercept	Correlation Coefficient	Range of Samples	n
Glucose					
Serum/Plasma	0.99	1.6 mg/dL	0.998	20 - 415	239*
Cerebrospinal Fluid	1.05	-1.2 mg/dL	0.996	3 - 260	60
Urea Nitrogen					
Serum/Plasma	1.01	-0.1 mg/dL	0.996	4 - 80	231**

* n = 239; 120 serum and 119 plasma
** n = 231; 118 serum and 113 plasma

Lorraine H Piestrak

Lorraine H. Piestrak
Quality Assurance and Compliance Manager

Date: Sept 22, 1998

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 22 1999

Ms. Lorraine H. Piestrak
Quality Assurance and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K983344
Trade Name: Dade Behring QuikLYTE™ MetaboLYTE Cartridge
Regulatory Class: II
Product Code: CGA, CDN
Dated: April 12, 1999
Received: April 13, 1999

Dear Ms. Piestrak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Steven Gutman

Steven I. Gutman, M.D, M.B.A
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: Dade Behring QuikLYTE™ MetaboLYTE cartridge

Indications for Use: The Dade Behring QuikLYTE™ MetaboLYTE cartridge is a sub-system on the Dimension® XL or RxL clinical chemistry analyzer. It performs two *in vitro* diagnostic tests, with these indications for use:

Glucose

Measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Urea Nitrogen

Measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K983344

Lorraine H Piestrak

Lorraine H. Piestrak
Quality Assurance and
Compliance Manager

Sept 22, 1998

Date

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K 983344

510(k) Number

Jean Cooper

Division Sign-Off
Office of Device Evaluation

✓ prescription use