K993536

NOV - 4 1999

Special 510(k): Device Modification Summary
Bio-Rad CODA Neonatal GALT Assay

Submitter:

Bio-Rad Laboratories, Inc.
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Contact Person:

Elizabeth Tang
Regulatory Affairs Specialist

Date of Summary Preparation: October 18, 1999

Device Name: Bio-Rad CODA Neonatal GALT Assay

Classification Name: Galactose-1-phosphate uridyl transferase test system

Predicate Device:

Microplate Neonatal GALT Assay
K998027
Bio-Rad Laboratories, Inc.

RADIAS GALT Assay
K961432
Bio-Rad Laboratories, Inc.

Statement of Intended Use: This assay is for the qualitative determination of galactose-1-phosphate uridyl transferase activity in dried blood spot samples using the Bio-Rad CODA Analyzer. Measurements of GALT are used in the diagnosis and treatment of the hereditary disease galactosemia (disorder of galactose metabolism) in infants.

For in vitro diagnostic use only.

Description of Device

The CODA GALT assay utilizes dried blood spot samples (DBS) eluted in a medium containing β-nicotinamide adenine dinucleotide phosphate (NADP), galactose-1-phosphate, uridine-5′-diphosphoglucose (UDPG), and a tetrazolium salt. During the manual elution step, GALT present in the specimen converts galactose-1-phosphate to glucose-1-phosphate, with the eventual reduction of NADP to NADPH.

After elution, the samples are placed on the CODA instrument and an aliquot of the eluate is transferred to a microwell. The optical density (OD) is read, then Enzyme Reagent is added.

During the incubation that follows, the Enzyme Reagent converts NADPH generated by GALT and endogenous red cell enzymes to NADP, and the tetrazolium salt to a colored formazan dye which is detected at 570 nm. The OD is read again and the difference between the two OD readings is determined. GALT activity, in units/g hemoglobin or units/liter blood, is calculated from the difference in signal between the two absorbance readings. A unit is defined as the quantity of GALT that catalyzes the formation of 1 micromole of UDP galactose per gram of hemoglobin or per Liter blood per hour at 37°C. An external calibrator is not necessary because enzyme activity is measured directly with substrates in excess.
The CODA instrument is an integrated immunoassay analyzer intended for the automation of microplate based assays for in vitro diagnostic use.

Testing To Establish Substantial Equivalence

To establish substantial equivalence to an existing device, and thus establish the safety and effectiveness, the CODA Neonatal GALT Assay is compared to the Microplate Neonatal GALT Assay. A review of the intended use of each system shows them to be the same. The only differences between the protocols are the size of dried blood spots and volume of Substrate/Color reagent used. No significant changes were made in the assay reagents or procedure.

The CODA assay will use the same kit configuration as the 510(k) cleared Microplate GALT Assay (#K990827). Those using the kit for the CODA application will follow the instructions of a separate CODA application instruction note. This note will refer them to the main kit insert for all other information about the assay.

Performance Characteristics

Performance Tests	Acceptance Criteria	CODA Assay	Microplate Assay
Concordance	100%	100%(to Manual)	NA
Analytical Sensitivity	< 1.0 U/g Hb	0.31 U/g Hb	0.64 U/g Hb
Within-run Precision	< 12 %	6.2% - 8.8%	4.3% - 10.6%
Total Precision	< 15 %	5.8% - 12.5%	7.0% - 11.8%
Interference of bilirubin, triglycerides, and protein	No Interference	No Interference	No Interference

When considering the similarities of the intended use, general characteristics of the two assays, the use of the same technology and the excellent concordance between the two methods, it can be concluded that the Microplate GALT Test and the CODA Neonatal GALT Assay are substantially equivalent. Based on the establishment of substantial equivalence, the safety and effectiveness of the CODA Neonatal GALT Assay is confirmed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 4 1999

Ms. Elizabeth Tang
Regulatory Affairs Specialist
Bio-Rad Laboratories, Inc.
Diagnostics Group
4000 Alfred Nobel Drive
Hercules, California 94547

Re: K993536
Trade Name: Bio-Rad CODA® Neonatal GALT Assay
Regulatory Class: II
Product Code: KQP
Dated: October 18, 1999
Received: October 19, 1999

Dear Ms. Tang:

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

Statement of Indications for Use

510(k) Number: K993536

Device Name: Bio-Rad CODA Neonatal GALT Assay

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For in vitro diagnostic use only.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993536

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescriptive Use ✓ OR Over-The-counter Use _____
(Per 21 CFR 801.109)