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510(k) Summary

K061839

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.

Submitter's Name: George M. Plummer
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101
302-631-9798
302-631-6299 (fax)

Date of Preparation: June 28, 2006

Name of Products: DBIL Flex® reagent cartridge

FDA Classification Name: Bilirubin (total or direct) test system

Predicate Device: Dade Behring DBIL Flex® reagent cartridge (k862359)

Device Description:

Diazotized sulfanilic acid is formed by combining sodium nitrite and sulfanilic acid at low pH. The sample is diluted in 0.5M HCl. A blank reading is taken to eliminate interference from non-bilirubin pigments. Upon addition of the diazotized sulfanilic acid, the conjugated bilirubin is converted to diazo-bilirubin, a red chromophore which absorbs at 540 nm and is measured using a bichromatic (540, 700 nm) endpoint technique.

Conjugated bilirubin + Diazotized sulfanilic acid ———> Red chromophore (absorbs at 540 nm)

Intended Use:

The DBIL method is an *in vitro* diagnostic test for the quantitative measurement of direct (conjugated) bilirubin in human serum and plasma on the Dimension Vista™ System. Measurements of direct bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder disease.

Comparison to the predicate device:

The DBIL Flex® reagent cartridge is substantially equivalent in intended use, principle and performance to the predicate Dade Behring DBIL assay, k862359. The assay is an *in vitro* assay with intended use for the measurement of direct bilirubin in human serum and plasma.

A summary of the features of the predicate and the Dimension Vista™ DBIL Flex® reagent cartridge assay is provided in the following chart. Although the intended use statement has been

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modified for the test assay to align with CFR 862.1110, there are no different claims for the test assay.

Attribute	Dimension® DBIL Assay (k862359)	Dimension Vista™ DBIL
Intended Use	The DBIL method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of direct (conjugated) bilirubin in serum and plasma.	The DBIL method is an *in vitro* diagnostic test for the quantitative measurement of direct (conjugated) bilirubin in human serum and plasma on the Dimension Vista™ System. Measurements of direct bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder disease.
Sample type	Human serum and plasma	Human serum and plasma
Methodology	Photometric (diazo chemistry)	Photometric (diazo chemistry)
Detection	Bichromatic (540, 700 nm)	Bichromatic (540, 700 nm)
Sample volume	31 uL	5 uL
Hemoglobin Flag	Yes	Yes
Analytical Sensitivity	Not provided	0.05 mg/dL
Repeatability	4.7 %CV at 5 mg/dL	9.1%CV @ 0.4 mg/dL 2.1%CV @ 5.9 mg/dL
Reference Interval	< 0.3 mg/dL	<0.2 g/dL

Comments on Substantial Equivalence:
Testing results demonstrate that the Dimension Vista™ DBIL Flex® reagent cartridge is equivalent to the predicate device. Method comparison results provided a slope of 0.97, intercept of 0.01 mg/dL and correlation of 0.999.

Conclusion:
The Dimension Vista™ DBIL Flex® reagent cartridge is substantially equivalent in principle and performance to the predicate product.

George M. Plummer
Quality Assurance and Compliance Manager
Date: June 28, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. George M. Plummer
Dade Behring, Inc.
P.O. Box 6101, Mailstop 514
Newark, DE 19714

Re: k061839
Trade/Device Name: DBIL Flex® reagent cartridge
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG
Dated: June 28, 2006
Received: June 29, 2006

Dear Mr. Plummer

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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 Statement

510(k) Number (if known): K061839

Device Name:

DBIL Flex® reagent cartridge

Indications for Use:

The DBIL method is an *in vitro* diagnostic test for the quantitative measurement of direct (conjugated) bilirubin in human serum and plasma on the Dimension Vista™ System. Measurements of direct bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder disease.

Prescription Use __X__ (Per 21 CRF 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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

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