K061719

510(k) Summary

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:

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AUG 25 2006

Date of Preparation: June 16, 2006

Name of Products: Dimension Vista™ TBIL Flex® reagent cartridge
Dimension Vista™ TDBIL Calibrator

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

Predicate Device: Dade Behring Dimension® TBIL Flex® reagent cartridge and TBIL/DBIL Calibrator (k861700)

Device Description:

TBIL Flex® reagent cartridge
Diazotized sulfanilic acid is formed by combining sodium nitrite and sulfanilic acid at low pH. Bilirubin (unconjugated) in the sample is solubilized by dilution in a mixture of caffeine/benzoate/acetate/EDTA. Upon addition of the diazotized sulfanilic acid, the solubilized bilirubin including conjugated bilirubins (mono and diglucoronides) and the delta form (biliprotein-bilirubin covalently bound to albumin) is converted to diazo-bilirubin, a red chromophore representing the total bilirubin which absorbs at 540 nm and is measured using a bichromatic (540, 700 nm) endpoint technique. A sample blank correction is used.

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

Total bilirubin and Direct bilirubin calibrator.
The TDBIL calibrator is a two level calibrator. Level 1, purified water, is provided through the on-board Dimension Vista™ system. Level 2 is a lyophilized human serum based material spiked with ditaurobilirubin and traceable to NIST Standard Reference Material 916a.

Intended Use:

TBIL Flex® reagent cartridge:
The TBIL method is an *in vitro* diagnostic test for the quantitative measurement of total bilirubin in human serum and plasma on the Dimension Vista™ System. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic hematological and metabolic disorders, including hepatitis and gall bladder disease.

TDBIL Calibrator:
The TDBIL CAL is an *in vitro* diagnostic product for calibration of the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista™ System.

Comparison to the predicate device:

The TBIL Flex® reagent cartridge and TDBIL Calibrator are substantially equivalent in intended use, principle and performance to the predicate Dade Behring TBIL assay and TBIL/DBIL Calibrator, k861700. The assays are *in vitro* assays with intended use for the measurement of total bilirubin in human serum and plasma. Both calibrators are for use of calibration of the total and direct bilirubin *in vitro* assays.

A summary of the features of the predicate and Dimension Vista™ TBIL Flex® reagent cartridge assays is provided in the following chart. Although the intended use statements have been modified for the test assay to align with CFR 862.1110, there are no different claims for the test assay.

Attribute	**Dimension® TBIL Assay (predicate)**	**Dimension Vista™ TBIL Assay**
Intended Use	The TBIL method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of total bilirubin in serum and plasma.	The TBIL method is an *in vitro* diagnostic test for the quantitative measurement of total bilirubin in human serum and plasma on the Dimension Vista™ System. Measurements of total 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	28 uL	5 uL
Hemoglobin Correction	Up to 500 mg/dL Hemoblobin	Up to 1000 mg/dL Hemoglobin
Analytical Sensitivity	Not provided	0.1 mg/dL
Within Lab Precision	2.4%CV at 0.9 mg/dL 9.6%CV @ 18.9 mg/dL	5%CV @ 0.9 mg/dL 2.9%CV @ 19.3 mg/dL
Reference Interval	< 1 mg/dL	<1 mg/dL

A summary of the features of the predicate and Dade Behring Dimension TDBIL calibrator is provided in the following chart.

Attribute	**Dimension® TBIL/DBIL Calibrator (predicate)**	**Dimension Vista™ TDBIL Calibrator**
Intended Use	The Dimension® Bilirubin Calibrator is an *in vitro* diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods. This product was designed to meet the needs of users to assure accurate results over the assay range of these methods.	The TDBIL CAL is an *in vitro* diagnostic product for calibration of the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista™ System.
Analyte	Ditaurobilirubin	Ditaurobilirubin
Matrix	Human serum	Human serum
Levels Bilirubin concentration (mg/dL) Total (TBIL) Direct (DBIL)	Three L1 (0.8), L2 (9.4), L3 (21) L1 (0.6), L2 (6.9), L3 (14.5)	One Level 2 (27.5) Level 2 (19.25) On-board purified system water is used for level 1.
Form	Lyophilized	Lyophilized
Volume	6 vials, 2 vials each level, 1 mL each vial (hydrated volume)	3 vials, 1mL each vial (hydrated volume).

Comments on Substantial Equivalence:
Testing results demonstrate that the Dimension Vista™ TBIL Flex® reagent cartridge and the associated TDBIL Calibrator are equivalent to the predicate devices. Method comparison results provided a slope of 0.94, intercept of 0.4 mg/dL and correlation of 0.999.

Conclusion:
The Dimension Vista™ TBIL Flex® reagent cartridge and the associated TDBIL Calibrator are substantially equivalent in principle and performance to the predicate products.

George M. Plummer
Quality Assurance and Compliance Manager
Date: June 16, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 25 2006

George M. Plummer
Regulatory Affairs and Compliance Manager
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Re: k061719
Trade/Device Name: TBIL Flex® reagent cartridge
TDBIL Calibrator
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG, JIT
Dated: June 16, 2006
Received: June 19, 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): k061719

Device Name:

TBIL Flex® reagent cartridge
TDBIL Calibrator

Indications for Use:

TBIL Flex® reagent cartridge:
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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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional Format 1-2-96) k061719