APR 6 2006

K060628

510(k) Summary of Safety and Effectiveness Information

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

Date of Preparation: March 8, 2006

Name of Products:

TBI Flex® reagent cartridge
DBI Flex® reagent cartridge
TBI/DBI Calibrator

FDA Classification Name:

Bilirubin (total or direct) test system
Bilirubin Calibrator

Predicate Device:

Dade Behring TBIL Flex® reagent cartridge (k861700)
Dade Behring DBIL Flex® reagent cartridge (k862359)
Dade Behring TBIL/DBIL Calibrator (k861700)

Device Description

Total Bilirubin/Direct Bilirubin reagents.
There is no change in the device operating principle or reagents which comprise the total and direct Flex® reagent cartridges with this revision.

TBI 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)

DBI Flex® reagent cartridge
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)

Total bilirubin and Direct bilirubin calibrator.
Purified water will be used as the low level calibrator instead of a low concentration of ditauro-bilirubin. This change was made to prevent lot to lot shifts in quality control recovery at the low end of the assay.

Intended Use:

TBI Flex® reagent cartridge:
The TBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure total bilirubin in human serum and plasma. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder disease.

DBI Flex® reagent cartridge:
The DBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure direct bilirubin in human serum and plasma. Measurements of direct bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder disease.

TBI/DBI Calibrator:
The Dimension® Bilirubin Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Direct Bilirubin (DBI) and Total Bilirubin (TBI) methods for the Dimension® clinical chemistry system. This product was designed to meet the needs of users to assure accurate results over the assay range of these methods.

Comparison to the predicate device:

The TBI, DBI Flex® reagent cartridges and TBI/DBI Calibrator are substantially equivalent in intended use, principle and performance to the original Dade Behring TBIL, DBIL assays, k861700 and k862359 respectively and TBIL/DBIL Calibrator, k 861700. See Appendix A and B for copies of the product inserts. The assays are *in vitro* assays with intended uses for the measurement of total and direct 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 Dade Behring Dimension TBI and DBI Flex® reagent cartridge and the predicate Dade Behring TBIL and DBIL Flex® reagent cartridge assays is provided in the following chart. Although the intended use statements have been modified to align with CFR 862.1110, there are no new claims for the assay.

Attribute	TBIL (original assay)	TBI (revised assay)	DBIL (original assay)	DBI (revised 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 TBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure total bilirubin in human serum and plasma. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder disease.	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 DBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure direct bilirubin in human serum and plasma. 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	Human serum and plasma	Human serum and plasma
Methodology	Photometric (diazo chemistry)	Photometric (diazo chemistry)	Photometric (diazo chemistry)	Photometric (diazo chemistry)
Detection	Bichromatic (540, 700 nm)	Bichromatic (540, 700 nm)	Bichromatic (540, 700 nm)	Bichromatic (540, 700 nm)
Sample volume	28 uL	10 uL	31 uL	10 uL
Hemoglobin Correction	Up to 500 mg/dL	Up to 1000 mg/dL	No	Up to 100 mg/dL
Hemoglobin Flag	Yes	Yes	No	Yes

A summary of the features of the Dade Behring Dimension TBI/DBI calibrator cartridge and the predicate Dade Behring TBIL/DBIL calibrator is provided in the following chart.

Attribute	Original Calibrator	Revised 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 Dimension® Bilirubin Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Direct Bilirubin (DBI) and Total Bilirubin (TBI) methods for the Dimension® clinical chemistry system. This product was designed to meet the needs of users to assure accurate results over the assay range of these methods.
Analyte	Ditauro-bilirubin	Ditauro-bilirubin
Matrix	Human serum	Human serum
Levels Bilirubin concentration (mg/dL) Total Direct	Three L1 (0.8), L2 (10), L3 (22) L1 (0.6), L2 (7), L3 (15)	Three L1 (0), L2 (10), L3 (25) L1 (0), L2 (7), L3 (17.5)
Form	Lyophilized	Lyophilized
Volume	6 vials, 2 vials each level, 1 mL each vial (hydrated volume)	4 vials, 2 vials each level, 1 ml each vial (hydrated volume). Purified water is used for level 0 and not supplied by Dade Behring.

Comments on Substantial Equivalence:
Testing versus the design input criteria and the results of the risk analysis demonstrate that the revised TBI Flex® reagent cartridge, DBI Flex® reagent cartridge and the associated TBI/DBI Calibrator are equivalent to the predicate devices, the current design products.

Conclusion:
The revised TBI Flex® reagent cartridge, DBI Flex® reagent cartridge and the associated TBI/DBI Calibrator are substantially equivalent in principle and performance to the current design products.

George M. Plummer
Quality Assurance and Compliance Manager
Date: March 8, 2006

Revised Product Premarketing Notification
[Ref: F, D &C Act, Section 510(k)]

Device Name:
TBI Flex® reagent cartridge
DBI Flex® reagent cartridge
TBI/DBI Calibrator

Applicant:
George M. Plummer
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
Building 500, Mailbox 514
P.O. Box 6101
Newark, DE 19714-6101
(302) 631-9798
(302) 631-6299 (Fax)

Manufactured By:
Dade Behring Inc.
1717 Deerfield Road
P.O. Box 778
Deerfield, IL 60015-0778
Owner/Operator No. 9017031

Manufactured At:
Dade Behring Inc.
Chemistry/Immunochemistry Group
Route 896
P.O. Box 6101
Newark, DE 19702
Establishment Registration No. 2517506

Date of Submission: March 8, 2006

Original Device 510 (k) Numbers:
TBIL Flex® reagent cartridge: k861700
DBIl Flex® reagent cartridge: k862359
TBIL/DBIL Calibrator: k861700

Classification:
The FDA has classified total and direct Bilirubin Test Systems as Class II in 21 CFR 862.1110 and Bilirubin Calibrators as Class II in 21 CFR 862.1150.

Standards and Guidance Documents:
The following voluntary standards or guidance documents were used in determining safety and effectiveness of the devices:

- CLSI/NCCLS EP5-A2, 2004, Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline-Second Edition
- CLSI/NCCLS EP9-A2, 2002, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition
- CLSI/NCCLS C28-A2, 2002 How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition
- CLSI/NCCLS EP7- A, 2002, Interference Testing in Clinical Chemistry; Approved Guideline
- General Principles of Software Validation: Final Guidance for Industry and FDA Staff, January, 11, 2002.
- ISO 14971-2000, Medical devices – Application of risk management to medical devices

Proposed Labels/Labeling:

A copy of the labels and labeling for the revised TBI and DBI Flex® reagent cartridges and TBI/DBI Calibrator is provided in Appendix A. A copy of the predicate labeling is provided in Appendix B.

Intended Use:

TBI Flex® reagent cartridge:

The TBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure total bilirubin in human serum and plasma. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder disease.

DBI Flex® reagent cartridge:

The DBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure direct bilirubin in human serum and plasma. Measurements of direct bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder disease.

TBI/DBI Calibrator:

The Dimension® Bilirubin Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Direct Bilirubin (DBI) and Total Bilirubin (TBI) methods for the Dimension® clinical chemistry system. This product was designed to meet the needs of users to assure accurate results over the assay range of these methods.

Comparison to the predicate device:

The TBI, DBI Flex® reagent cartridges and TBI/DBI Calibrator are substantially equivalent in intended use, principle and performance to the original Dade Behring TBIL, DBIL assays, k861700 and k862359 respectively and TBIL/DBIL Calibrator, k 861700. See Appendix A and B for copies of the product inserts. The assays are *in vitro* assays with intended uses for the measurement of total and direct 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 Dade Behring Dimension TBI and DBI Flex® reagent cartridge and the predicate Dade Behring TBIL and DBIL Flex® reagent cartridge assays is provided in the following chart. Although the intended use statements have been modified to align with CFR 862.1110, there are no new claims for the assay.

Attribute	**TBIL (original assay)**	**TBI (revised assay)**	**DBIL (original assay)**	**DBI (revised 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 TBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure total bilirubin in human serum and plasma. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder disease.	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 DBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure direct bilirubin in human serum and plasma. 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	Human serum and plasma	Human serum and plasma
Methodology	Photometric (diazo chemistry)	Photometric (diazo chemistry)	Photometric (diazo chemistry)	Photometric (diazo chemistry)
Detection	Bichromatic (540, 700 nm)	Bichromatic (540, 700 nm)	Bichromatic (540, 700 nm)	Bichromatic (540, 700 nm)
Sample volume	28 uL	10 uL	31 uL	10 uL
Hemoglobin Correction	Up to 500 mg/dL	Up to 1000 mg/dL	No	Up to 100 mg/dL
Hemoglobin Flag	Yes	Yes	No	Yes

A summary of the features of the Dade Behring Dimension TBI/DBI calibrator cartridge and the predicate Dade Behring TBIL/DBIL calibrator is provided in the following chart.

Attribute	Original Calibrator	Revised 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 Dimension® Bilirubin Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Direct Bilirubin (DBI) and Total Bilirubin (TBI) methods for the Dimension® clinical chemistry system. This product was designed to meet the needs of users to assure accurate results over the assay range of these methods.
Analyte	Ditauro-bilirubin	Ditauro-bilirubin
Matrix	Human serum	Human serum
Levels Bilirubin concentration (mg/dL) Total Direct	Three L1 (0.8), L2 (10), L3 (22) L1 (0.6), L2 (7), L3 (15)	Three L1 (0), L2 (10), L3 (25) L1 (0), L2 (7), L3 (17.5)
Form	Lyophilized	Lyophilized
Volume	6 vials, 2 vials each level, 1 mL each vial (hydrated volume)	4 vials, 2 vials each level, 1 ml each vial (hydrated volume). Purified water is used for level 0 and not supplied by Dade Behring.

Device Description

1. Total Bilirubin and Direct Bilirubin Flex® reagent cartridge.
   There are no changes in the device operating principle or reagents which comprise the total and direct Flex® reagent cartridges with this revision.

   A. TBI 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)

B. DBI Flex® reagent cartridge
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)

2. Total bilirubin and Direct bilirubin calibrator.
Purified water will be used as the low level calibrator instead of a low concentration of ditauro-bilirubin. This change was made to prevent lot to lot shifts in quality control recovery at the low end of the assay.

Design Control Activities

1. Design Development
For the revised TBIL, DBIL assays and the associated TBIL/DBIL calibrator, we followed the standard Dade Behring new/revised product development process, an integrated structured approach to product development that ensures products will meet design goals, customer needs and global regulatory and compliance requirements. A cross-functional product development team (R&D, Manufacturing, Marketing, Technical Support and Regulatory), referred to as the Core Team, was assigned to develop the revised assays and calibrator. The design control processes that were followed for the revised assays and calibrator are described in the following bullet points:

   A. Development proceeds through set stage gates with deliverables required to proceed to the next stage. A review is conducted at each stage gate with the Product Approval Committee (PAC) comprised of functional management to assess readiness to advance to the next stage. The review is conducted versus standard and project specific deliverables.
   B. A risk analysis is conducted to asses the impact of the modification on the device and its components. The risk analysis is reviewed periodically throughout the development process to ensure progress is attained on any required verification and/or validation activities resulting from the analysis.
   C. Product design input requirements (DIR) and acceptance criteria are identified.
   D. Technology is validated to produce the product and initial design in the early product development stages.
   E. Design improvement, design verification, design validation and development of support processes are completed in subsequent development stages.
   F. Design reviews are conducted periodically to ensure continued compliance to design goals and review status of progress of the project.

2. Risk Analysis
The Dade Behring risk management process is designed to align with ISO 14971-2000, Medical devices – Application of risk management to medical devices. A summary of the

risk analysis process, the verification, validation, and test activities, and the acceptance criteria and results is provided in Appendix C.

3. Design Testing and Evaluation

Design Input Requirements (DIRs) are developed early in the product development process. The product is evaluated versus the DIR throughout the development process. Three validation lots of the revised TBI and DBI Flex® reagent cartridges and associated TBI/DBI calibrator were manufactured at full commercial scale under standard manufacturing conditions. These qualification lots were evaluated versus the DIR requirements as described below:

   A. Method Comparison: Split-sample correlation study designed to compare the accuracy of the qualification lots to that of a commercial control lot using more than 100 frozen serum samples obtained from clinical laboratories.
   B. Open-Well Stability: Comparison of results with reagents after Flex® well puncture vs. fresh reagents to challenge the open-well stability requirement.
   C. Interference: Tests the affect of a specific set of potential interfering materials that are listed in the product insert in Appendix A.
   D. Recovery: Tests the recovery across the assay range using a set of samples prepared by mixing a high concentration of total bilirubin or direct bilirubin and a blank sample at various ratios.
   E. Analytical Sensitivity: Tests the analytical sensitivity of the method (defined as 2 times the standard deviation obtained with a sample that contains 0 mg/dL bilirbuin) by running 20 replicate batches to estimate the standard deviation.
   F. Precision: Tests within-run and total reproducibility using an ANOVA approach in compliance with CLIS/NCCLS EP-5A2.
   G. Reference Range: Tests that confirm the existing predicate product reference range.
   H. Shelf Life Stability: Tests that demonstrate the real time product stability at normal product temperature storage conditions

Details of the DIR acceptance criteria may be found in Appendix D.

4. Verification and Validation Activities

Performance studies were conducted internally versus the DIR goals described above. All goals were achieved.

5. Declaration of Conformity

A declaration of conformity is provided in Appendix E. This declaration provides a statement that:

   A. all verification and validation activities were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met
   B. the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Comments on Substantial Equivalence/Conclusion:

Testing versus the design input criteria and the results of the risk analysis demonstrate that the revised TBI Flex® reagent cartridge, DBI Flex® reagent cartridge and the associated TBI/DBI Calibrator are equivalent to the predicate devices, the current design products. The revised products are substantially equivalent in principle and performance to the current design products.

George M. Plummer
Regulatory Affairs and Compliance Manager
Date: March 8, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 3 2006

George Plummer
Dade Behring, Inc.
Glasgow Business Community
Bldg 500, MS 514 P.O. Box 6101
Newark, DE 19714 6101

Re: k060628
Trade/Device Name: Dade Behring Dimension Total and Direct Bilirubin Assays.
Regulation Number: 862.1110
Regulation Name: Bilirubin (total or direct) test system.
Regulatory Class: II
Product Code: CIG, JIS
Dated: March 8, 2006
Received: March 9, 2006

Dear Mr. Plummer:

This letter corrects our substantially equivalent letter of April 6, 2006.

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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

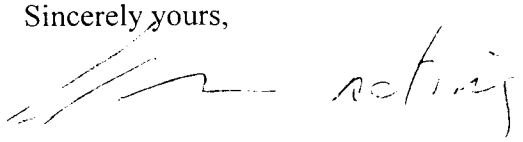
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. 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): K060628

Device Name:

TBI Flex® reagent cartridge; DBI Flex® reagent cartridge;TBI/DBI Bilirubin Calibrator

Indications for Use:

TBI Flex® reagent cartridge:

The TBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure total bilirubin in human serum and plasma. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder disease.

DBI Flex® reagent cartridge:

The DBI method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure direct bilirubin in human serum and plasma. Measurements of direct bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder disease.

TBI/DBI Calibrator:

The Dimension® Bilirubin Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Direct Bilirubin (DBI) and Total Bilirubin (TBI) methods for the Dimension® clinical chemistry system. This product was designed to meet the needs of users to assure accurate results over the assay range of these methods.

George M. Plummer
Regulatory Affairs and
Compliance Manager

March 8, 2006

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CRF 801 Subpart D) (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 Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K060628