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510(k) Summary for the
Dimension® IRON Flex® reagent cartridge (DF85)

A. 510(k) Number: K060264

B. Analyte: Total iron

C. Type of Test: Quantitative

D. Applicant:
Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Contact: Andrea M. Tasker, Regulatory Affairs and Compliance Manager
(302) 631-9454

Date of Preparation: January 30, 2006

E. Proprietary and Established Names:
Dimension® Iron Flex® reagent cartridge (IRON-DF85)

F. Regulatory Information:

1. Regulation section: 21 CFR §862.1410 Iron (non-heme) test system

2. Classification: Class I

3. Product Code: JIY

4. Panel: Chemistry (75)

G. Intended Use:
1. Intended for Use:
The IRON method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure iron in human serum and plasma.

2. Indications for Use: The IRON method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure iron in human serum and plasma. Iron measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia and other disorders of iron metabolism.

3. Special condition for use statement(s): none

4. Special instrument Requirements: Dimension® clinical chemistry system

H. Device Description:
The Dimension® IRON Flex® reagent cartridge (DF85) is an in vitro diagnostic device that consists of prepackaged reagents in a plastic eight well cartridge for use on the Dade Behring Dimension® clinical chemistry system for the quantitative determination of iron in serum and plasma.

I. Substantial Equivalence Information:
1. Predicate Device: Dimension® IRN Iron Flex® reagent cartridge (DF49A)

2. Predicate K Number(s): K944093

3. Comparison with Predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quantitative determination of total iron	same
Reagent components	Ferene® (chromophore) Thiourea (prevent Cu interference) Ascorbic acid (reducing agent)	same
Measurement method	Bi-chromatic endpoint measurement (600 and 700 nm)	same
Calibration	Three point linear calibration	same
Analytical Range	0 to 1,000 µg/dL	same
Standardization	NIST SRM 937	same
Differences		
Item	**Device**	**Predicate**
Matrix	Serum or heparinized plasma	Serum only

J. Standard/Guidance Document Referenced
1. Guidance;
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004
Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy, 12/11/2003
Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff, 08/12/2005

2. Standards;

GP22-A	Continuous Quality Improvement Essential Management Approaches
ISO 15223	Medical devices – Symbols to be used with medical device labeling and information to be supplied
ISO 14971-2000	Application of risk analysis to Medical devices
EP7-A	Interference Testing in Clinical Chemistry
EP5-A2	Evaluation of Precision Performance of Clinical Chemistry Devices
CEN 13640	Stability testing of In-Vitro Diagnostic Devices

K. Test Principle:

The automated Dimension® IRON method is an adaptation of direct iron assays using the chromophore Ferene ® . Under acidic conditions, iron (Fe+++) bound to the protein transferrin is released. In the presence of the reducing agent ascorbic acid, (Fe+++) is reduced to (Fe++). (Fe ++) forms a blue complex with 3-(2-pyridyl)-5,6-bis-2-(5-furyl sulfonic acid)-1,2,4-triazine, disodium salt (Ferene®). The absorbance of the complex, measured using a bichromatic (600, 700 nm) endpoint technique, is directly proportional to the concentration of transferrin-bound iron in the serum.

L . Performance Characteristics:

1. Precision/Reproducibility:

Reproducibility testing was done in accordance with the CLSI/NCCLS Approved Guideline for Evaluation of Precision Performance of Clinical Chemistry Devices (EP5-A2). Commercial controls and serum and plasma pools were analyzed in duplicate twice a day for 20 days. The repeatability and within-lab standard deviations were calculated by analysis of variance method.

Reproducibility[a,b]

Material	Mean µg/dL	Mean [µmol/L]	Standard Deviation (%CV) Repeatability	Standard Deviation (%CV) Within-lab
Plasma pool	101	18	0.5 [0.09] (0.5)	0.7 [0.13] (0.7)
Serum pool 1	95	16.9	0.5 [0.09] (0.5)	0.6 [0.11] (0.6)
Serum pool 2	316	56.6	1.5 [0.27] (0.5)	3.5 [0.63] (1.1)
Serum pool 3	533	95.4	2.4 [0.43] (0.5)	4.2 [0.75] (0.8)
BioRad Lyphochek® control Level 1	231	41.3	1.3 [0.23] (0.5)	1.6 [0.29] (0.7)
BioRad Lyphochek® control Level 2	50	8.9	0.5 [0.09] (1.1)	0.9 [0.16] (1.9)
BioRad Lyphochek® Anemia control Level 1	26	4.7	0.3 [0.05] (1.3)	0.5 [0.09] (1.9)
Reduced Sample Volume[c]				
Serum pool 1	103	18.5	0.7 [0.13] (0.6)	1.0 [0.18] (0.9)
Serum pool 2	316	56.6	1.5 [0.27] (0.5)	3.5 [0.63] (1.1)
Serum pool 3	530	94.9	2.9 [0.52] (0.5)	4.2 [0.75] (0.8)
BioRad Lyphochek® Anemia control Level 1	32	5.7	0.3 [0.05] (1.3)	0.5 [0.09] (1.9)
BioRad Multiqual® control Level 3	231	41.3	1.6 [0.29] (0.7)	2.2 [0.39] (0.9)

Lyphochek® and Multiqual® are registered trademarks of Bio-Rad Laboratories, Irvine, CA 92618.

a. Reproducibility testing was done in accordance with the CLSI/NCCLS Approved Guideline for Evaluation of Precision Performance of Quantitative Measurement Methods (EP5-A2, 2004).

b Specimens at each level were analyzed in duplicate, twice a day, for 20 days. The repeatability andwithin-lab standard deviations were calculated by analysis of variance method.

c. Using reduced sample size (25 uL).

2. Linearity/assay reportable range:

Solutions of NIST SRM 937 were prepared by sequential mixing to create equally spaced samples ranging from 0 to 2000 µg/dL iron. The linearity of iron on the Dimension® RxL by the Dimension® IRON assay was evaluated by comparing observed versus expected values across the expected range. A linear regression analysis was performed on the data and plotted. The observed linearity across the reportable range has a correlation coefficient of 0.999 (using Pearson correlation calculation), slope of 0.999, and an intercept of 0.178. The assay range claim is 5.0 µg/dL to1000 µg/dL.

3. Traceability (controls, calibrators, or method):
The recommended reference material for the Dimension® IRON method is the Dimension® IRON Calibrator (Cat. No. DC85). The assigned values of this product are standardized to SRM NIST 937 Iron Metal Clinical Standard which is a Standard Reference Material of the National Institute of Standards & Technology.

4. Detection limit:
The analytical sensitivity of Dimension® IRON is 5 µg/dL [0.9 µmol/L]. The analytical sensitivity represents the lowest concentration of iron that can be distinguished from zero. This sensitivity is defined as the mean value (n=20) plus two standard deviations of the low level (0 µg/dL [0 µmol/L] IRON Calibrator.

5. Analytical specificity:
Interference testing was performed according to the CLSI/NCCLS Protocol EP-7A. Systematic inaccuracies (bias) due to these substances are less than 10% at an iron concentration of 26 to 38 µg/dL [4.7 to 6.8 µmol/L] and 118 to 136 µg/dL [21.1 to 24.3 µmol/L]. A summary of potential interfering substances and the substances that do not interfere with the Dimension® IRON method when present in serum at the concentrations indicated can be found in the package insert.

6. Method comparison with predicate device:
A total of 147 samples were tested using the Dimension® IRON and IRN assays on a Dimension® RxL clinical chemistry system. 99 individual patient serum samples and 48 individual patient serum samples that were spiked with various amounts of NIST-937 reference iron material were tested. Studies were performed using routine methods for quality control, maintenance and calibration as described in the instrument instructions for use.

Linear regression analysis was performed using the SAS® System. The model equation for regression statistics is: Result of Dimension® system = (Slope x comparative method result) + Intercept. The range of IRON values in the correlation study was: 9 to 963 µg/dL. The linear regression statistics are presented in the table below.

Method Comparison

Comparative Method	Slope	Intercept ug/dL	Correlation Coefficient	n
Dimension® IRN (DF49A)	0.980	-0.488	0.9996	147

7. Matrix comparison

129 matched specimens of serum and heparinized plasma were drawn and processed by the IRON method on the Dimension® clinical chemistry system. Linear regression analysis showed excellent agreement between serum, lithium heparin plasma and sodium heparin plasma specimens. No clinically significant difference was observed between serum and plasma samples.

Sodium heparin plasma versus serum: n = 129, y = 0.988x + 0.804, r = 0.999
Lithium heparin plasma versus serum: n = 129, y = 0.985x + 1.42, r = 0.999
Lithium heparin plasma verus sodium heparin plasma: n = 129, y = 0.997x + 0.666, r = 0.999

8. Reference Interval

Males: 65-175 µg/dL [11.6-31.3 µmol/L][1]

Females: 50-170 µg/dL [9.0- 30.4 µmol/L][1]

Normal reference intervals can differ by as much as 35% between commercial iron methods[2], therefore it is advised that each laboratory establish its own expected values for iron as performed on the Dimension® system.

1. Kaplan LA, Psece AJ. Clinical Chemistry Theory, Analysis, and Correlation, 3rd ed. St. Louis; Mosby, Inc., 1996: p 699, 713-714.

2. Burtis, CA, Ashwood ER, Bruns DE. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis: Elsevier Saunders, 2005, 1186-1193.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 8 2006

Ms. Andrea Tasker
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
Glasgow Business Community
P.O. Box 6101, Bldg. 500, M/S 514
Newark, DE 19714-6101

Re: k060264
Trade/Device Name: Dimension® Iron Flex® reagent cartridge (IRON-DF85)
Regulation Number: 21 CFR§862.1410
Regulation Name: Iron (non-heme) test system
Regulatory Class: Class I
Product Code: JIY
Dated: January 30, 2006
Received: February 1, 2006

Dear Ms. Tasker:

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): k060264

Device Name:
Dimension® Iron Flex® reagent cartridge (IRON – DF85)

Indications for Use:

The IRON method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure iron in human serum and plasma. Iron measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia and other disorders of iron metabolism.

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Prescription Use ✓ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k060264