MAR 2 1 2007

510(k) Summary for
Dimension Vista™ STFR Flex® reagent cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L, M and H

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.

The assigned 510(k) number is: K063663

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information:
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: December 7, 2006

2. Device Name:
Dimension Vista™ STFR Flex® reagent cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Classification: Class II; Class II; Class I
Product Code: DDG; JIX; JJY
Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Devices:

Dade Behring N Latex sTFR– K053072
Dade Behring N Protein Standard SL – K012470
Dade Behring N/T Protein Control SL – K012468

4. Device Descriptions:

Dimension Vista™ STFR Flex® reagent cartridge
Polystyrene particles coated with monoclonal antibodies specific to human soluble transferrin receptor are aggregated when mixed with samples containing soluble transferrin receptor. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista™ Protein 1 Calibrator
Protein 1 Calibrator is a multi-analyte, liquid, human serum based product containing C3 Complement, C4 Complement, immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB) and Soluble Transferrin Receptor (STFR).

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are multi-analyte, liquid, human serum based products containing C3 complement, C4 complement, immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB) and soluble transferrin receptor (STFR).

5. Device Intended Uses:

Dimension Vista™ STFR Flex® reagent cartridge:
The STFR method is an *in vitro* diagnostic test for the quantitative determination of soluble transferrin receptor in human serum and heparinized plasma on the Dimension Vista® System. Measurements of soluble transferrin receptor aid in the diagnosis of malnutrition, acute inflammation, infection, and iron deficiency anemia.

Dimension Vista™ Protein 1 Calibrator:
PROT1 CAL is an *in vitro* diagnostic product for the calibration of the C3 Complement (C3), C4 Complement (C4), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM), Prealbumin (PREALB) and Soluble Transferrin Receptor (STFR), methods on the Dimension Vista® System.

Dimension Vista™ Protein 1 Control L, M and H:
PROT1 CON L, M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of C3 complement (C3), C4 complement (C4), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM), prealbumin (PREALB) and soluble transferrin receptor (STFR) on the Dimension Vista® System.

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista™ STFR assay, like Dade Behring N Latex sTfR is an *in vitro* diagnostic test for the quantitative measurement of soluble transferrin receptor in human serum and plasma.

7. Device Performance Characteristics:

The Dimension Vista™ STFR assay was compared to the Dade Behring N Latex sTfR assay on the BN ProSpec® System by evaluating serum and plasma samples with

concentrations ranging from 0.21 mg/L to 4.13 mg/L. Regression analysis of these results yielded the following equation.

Method Comparison Study

Comparative Method	n	Slope	Intercept mg/L	Correlation Coefficient
N Latex sTFR on the BN ProSpec® System	153	1.053	-0.078	0.997

8. Conclusion:

These studies demonstrate correlation and equivalent performance between the Dade Behring N Latex sTfR assay and the Dimension Vista™ STFR assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 1 2007

Ms. Kathleen A. Dray-Lyons
Regulatory Affairs & Compliance Manager
Dade Behring Inc.
PO Box 6101, M/S 514
Newark DE 19714- 6101

Re: k063663
Trade/Device Name: Dimension Vista™ STFR® Reagent Cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H
Regulation Number: 21 CFR§866.5880
Regulation Name: Transferrin Immunological Test System
Regulatory Class: Class II
Product Code: DDJ, JIX, JJY
Dated: February 12, 2007
Received: February 15, 2007

Dear Ms. Dray-Lyons:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: **Dimension Vista™ STFR Flex® reagent cartridge**
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Indications for Use:

Dimension Vista™ STFR Flex® reagent cartridge:
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Dimension Vista™ Protein 1 Control L, M and H
PROT1 CON L, M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of C3 Complement (C3), C4 Complement (C4), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM), prealbumin (PREALB) and Soluble Transferrin Receptor (STFR) on the Dimension Vista® System.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D)
Over-The-Counter-Use_____ (21 CFR 801)

(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

K063663

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