MAR 3 2006

K 053531

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: Lorraine H Piestrak
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: December 16, 2005

Name of Product:

Dimension Vista™ Free Thyroxine Flex® reagent cartridge (FT4)
Dimension Vista™ LOCI 1 Calibrator

FDA Classification Name:

Free Thyroxine test system	(Class II)
Calibrator, Secondary	(Class II)

Predicate Device:

The following table describes the predicate devices, device classification, regulation and product code associated with this pre-market notification:

New Product	Predicate Device	510(k) number	Device Class	Regulation	Product Code
Dimension Vista™ Free Thyroxine (FT4) Flex® reagent cartridge	ADVIA Centaur FrT4 assay	unknown	II	862.1695	CEC
Dimension Vista™ LOCI 1 Calibrator	Thyroid Calibrator	K970389	II	862.1150	JIT

Device Description:

The FT4 method is a homogenous, sequential, chemiluminescent immunoassay based on Luminescent Oxygen Channeling Immunoassay (LOCI™) technology. The LOCI™

reagents include two latex bead reagents and a biotinylated anti-T4 mouse monoclonal antibody. The first bead reagent (Chemibeads) is coated with triiodothyronine (T3), a naturally occurring, weaker binding analog of T4, and contains chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. In a first step, sample is incubated with biotinylated antibody which allows T4 from the sample to saturate a fraction of the biotinylated antibody that is directly related to the free T4 concentration. In a second step, T3 chemibeads are added and form bead/ biotinylated antibody immunocomplexes with the non-saturated fraction of the biotinylated antibody. Sensibeads are then added and bind to the biotin to form bead pair immunocomplexes. When illuminated by light at 680 nm, sensibeads convert dissolved oxygen in the reaction solution into the singlet oxygen form ($^1O_2$). In the bead pairs, the singlet oxygen diffuses ("channels") into chemibeads, triggering a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is an inverse function of the concentration of free T4 in the sample.

The Dimension Vista™ LOCI I Calibrator is a three level, liquid, multi-analyte product. This product's matrix is bovine serum albumin and it contains buffer, stabilizer and preservatives. Level A is a zero level, while levels B and C contain human thyroxine, triodothyronine and thyroid stimulating hormone. Values are assigned to the calibrator from a masterpool that is traceable through a patient correlation study to an existing comparative method for FT3 and FT4. The TSH value is referenced to the WHO standard, 2nd IRP 80/588, and confirmed with the 3rd IS 81/565.

Intended Use:

The Dimension Vista™ Free Thyroxine Flex® reagent cartridge (FT4) is an in-vitro diagnostic test for the quantitative measurement of Free thyroxine in human serum and plasma.

The Dimension Vista™ LOCI I Calibrator is an in-vitro diagnostic product intended for the calibration of Thyroid Stimulating Hormone (TSH), Free Triiodothyronine (FT3), and Free Thyroxine (FT4).

Comparison to Predicate Device:

Both the Dimension Vista™ Free Thyroxine Flex® reagent cartridge and the predicate Advia Centaur FrT4 assay employ prepackaged reagents for use on automated clinical chemistry test systems. A comparison of the important similarities and differences of these methods is provided in the following table:

Feature	Dimension Vista™ Free Thyroxine (FT4) Flex® reagent cartridge	ADVIA Centaur FrT4 assay
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
Sample Type	Serum and Plasma	serum
Assay Range	0.1 - 8.0 ng/dL	0.1 - 12.0 ng/dL
Technology	chemiluminescent	chemiluminescent
Sample Size	10 µL	25 µL
Antibody	Anti - T4 mouse monoclonal	Anti -T4 rabbit polyclonal

Feature	Dimension Vista™ LOCI I Calibrator	Dimension® Thyroid Calibrator
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
Analytes	FT4, TSH, FT3	FT4, TSH
Matrix	Bovine Serum Albumin	Bovine Serum Albumin
Form	liquid	liquid
Volume	A 2.5 mL per vial B 1.5 mL per vial C 2.0 mL per vial	2 mL per vial
Levels	3 levels	5 levels

Comments on Substantial Equivalence:

Split sample comparison between the Dimension Vista™ FT4 Flex™® reagent cartridge and ADVIA Centaur FrT4 assay gave the following correlation statistics, when tested with clinical patient samples:

Method Comparison Data
Dimension Vista™ FT4 vs. Predicate Method

Dimension Vista™	Predicate	Sample Type	Slope	Intercept	Correlation Coefficient (r)	n
FT4	ADVIA Centaur FrT4	Serum	1.03	0.02	0.983	108

Conclusion:

The Dimension Vista™ FT4 Flex® reagent cartridge with the associated LOCI I calibrator is substantially equivalent in principle and performance to the ADVIA Centaur FrT4 assay based on the split sample comparison discussed above.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
December 16, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 3 2006

Ms. Lorraine H. Piestrak
Regulatory Affairs & Compliance Manager
Dade Behring Inc.
PO Box 6101, M/S 514
Newark DE 19714- 6101

Re: k053531
Trade/Device Name: Dimension Vista™ Free Thyroxine Flex® reagent cartridge (FT4)
Dimension Vista™ LOCI 1 Calibrator
Regulation Number: 21 CFR§862.1695
Regulation Name: Free thyroxine test system
Regulatory Class: Class II
Product Code: CEC, JIT
Dated: December 16, 2005
Received: December 19, 2005

Dear Ms. Piestrak:

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

510(k) Number (if known): K053531

Device Name: Dimension Vista™ Free Thyroxine Flex® reagent cartridge (FT4)

Indications For Use:

The Dimension Vista™ Free Thyroxine Flex® reagent cartridge (FT4) is a device intended to measure Free (not protein bound) thyroxine (thyroid hormone) in serum and plasma. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid disease.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

510(k) K053531

Indications for Use

510(k) Number (if known): K053531

Device Name: Dimension Vista™ LOCI 1 Calibrator

Indications For Use:

The Dimension Vista™ LOCI I Calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of Free Thyroxine (FT4), Free Triiodothyronine (FT3), and Thyroid Stimulating Hormone (TSH) in human specimens.

Prescription Use _____X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

510(k) K053531