MAR 13 2008

510(k) Summary of Safety and Effectiveness
Dimension® EXL™ with LM clinical chemistry system,
Dimension® FT4L Flex® reagent cartridge and
LOCI® Thyroid Calibrator

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K073604

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

Manufacturer:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	February 18, 2008

2. Device Name / Classification

Dimension® EXL™ with LM clinical chemistry system / Class I
Dimension® FT4L Flex® reagent cartridge / Class II
LOCI® Thyroid Calibrator / Class II

3. Identification of the Predicate Device

Dimension® RxL Max® clinical chemistry system
(the Dimension® RxL Max is a family member of the Dimension® XL clinical chemistry system, which was cleared under K944093)
Dimension Vista™ FT4 Flex® reagent cartridge, K053531
Dimension Vista™ LOCI 1 Calibrator, K053531

4. Device Description

The Dimension® EXL™ with LM clinical chemistry system is a floor model, fully automated, microprocessor-controlled, integrated instrument system which uses prepackaged Dade Behring Flex® reagent cartridges to measure a variety of analytes in human body fluids. The system can process samples in random access, batch or stat modes.

The Dimension® FT4L Flex® reagent cartridge is an in vitro diagnostic device that consists of prepackaged reagents in a plastic eight-well cartridge for use on the Dimension® EXL™ with LM system.

The LOCI® Thyroid Calibrator is a liquid, bovine serum albumin based product containing thyroxine. There are four calibrator levels with target values of 0.8, 1.6, 4.0 and 8.4 ng/dL.

5. Device Intended Use

The FT4L method is an in vitro diagnostic test for the quantitative measurement of Free Thyroxine in human serum and plasma on the Dimension® EXL™ with LM system. Measurements of free thyroxine are used in the diagnosis and monitoring of thyroid disease.

The LOCI® Thyroid Calibrator is an in vitro diagnostic product for the calibration of the FT4L method on the Dimension® EXL™ with LM system.

The Dimension® EXL™ with LM system is an in vitro diagnostic device that is intended to measure a variety of analytes in human body fluids. The system utilizes photometric, turbidimetric, chemiluminescence and integrated ion selective multisensor technology for chemical and immunochemical applications for clinical use.

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

The Dimension® EXL™ with LM system is substantially equivalent in intended use and technological characteristics to the Dimension® RxL Max® system. Both instruments are fully automated, microprocessor-controlled integrated instruments with similar detection technologies and modes of operation.

The Dimension® FT4L Flex® reagent cartridge is substantially equivalent in intended use and technological characteristics to the Dimension® Vista FT4 Flex® reagent cartridge. Both devices use LOCI technology and are intended for use in the quantitative measurement of Free Thyroxine in human serum and plasma. The devices have identical measuring ranges of 0.1 – 8.0 ng/dL.

The LOCI® Thyroid Calibrator is substantially equivalent in intended use and technological characteristics to the Dimension® LOCI 1 Calibrator. Both calibrators use a matrix comprised of stripped bovine albumin spiked with USP-grade Thyroxine.

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Comparison Information

Method comparison studies were conducted on the Dimension® FT4L Flex® vs. the Dimension® Vista FT4 Flex® reagent cartridge using one hundred-and-eighty (180) serum samples. The data was analyzed using least squares linear regression. The Dimension® FT4L Flex® demonstrated excellent correlation to the predicate device as evidenced by a correlation coefficient = 0.999. The resulting regressions statistics are shown below.

Slope	0.97
95% CI	0.96 – 0.97
y-int	-0.03
r	0.999
Sy,x	0.08 ng/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dade Behring, Inc.
c/o Ms. Yuk-Ting Lewis,
Regulatory Affairs and Compliance Manager
P.O. Box 6101, M/S 514
Newark, DE 19714-6101

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Re: k073604
Trade/Device Name: Dimension® FT4L Flex® reagént cartridge LOCI® Thyroid Calibrator Dimension® EXL™ with LOCI® Module (LM) Clinical Chemistry System
Regulation Number: 21 CFR§ 862.1695
Regulation Name: Free thyroxine test system.
Regulatory Class: Class II
Product Code: CEC, JIT, JJE
Dated: December 20, 2007
Received: December 21, 2007

Dear Ms. Lewis:

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

K073604

Indication for Use

510(k) Number (if known): K073604

Device Name: Dimension® FT4L Flex® reagent cartridge
LOCI® Thyroid Calibrator
Dimension® EXL™ with LM clinical chemistry system

Indications For Use:

The FT4L method is an in vitro diagnostic test for the quantitative measurement of Free Thyroxine in human serum and plasma on the Dimension® EXL™ with LM system. Measurements of free thyroxine are used in the diagnosis and monitoring of thyroid disease.

The LOCI® Thyroid Calibrator is an in vitro diagnostic product for the calibration of the FT4L method on the Dimension® EXL™ with LM system.

The Dimension® EXL™ with LM system is an in vitro diagnostic device that is intended to measure a variety of analytes in human body fluids. The system utilizes photometric, turbidimetric, chemiluminescence and integrated ion selective multisensor technology for chemical and immunochemical applications for clinical use.

Prescription Use ___x___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073604