K032697

NOV - 7 2003

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 Piestrak
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Date of Preparation: August 29, 2003

Name of Product: Dimension® Total Triiodothyronine (T3) Calibrator (RC414)

FDA Classification Name: Calibrator

Predicate Device: Opus Total T3 Calibrator (K953160)

Device Description: The Dimension® Total Triiodothyronine (T3) Calibrator (RC414) is a liquid product. The kit consists of 10 vials, two each at levels 1 through 5. Level 1 vials contain 2 mL of stripped human serum. Vials for levels 2 through 5, contain 1 mL with concentrations of L-triiodothyronine in a stripped human serum base.

Intended use: The Dimension® Total Triiodothyronine (T3) Calibrator (RC414) is intended for use in the calibration of the Total Triiodothyronine (T3) method on the Dimension® clinical chemistry system with the Heterogeneous Immunoassay Module.

Comparison to Predicate Device:

	Dimension® T3 Calibrator	Opus Total T3 Calibrator
Intended Use	Calibrator	Calibrator
Analyte	T3	T3
Matrix	stripped human serum base	stripped human serum base
Form	liquid	liquid
Volume	2 mL per vial @ level 1 1 mL per vial @ levels 2-5	2 mL per vial @ level 1 1 mL per vial @ levels 2-6
Levels	5 levels @ 0, 1, 2, 4, 6.5 ng/ml	6 levels @ 0, 0.5, 1, 2, 4, 6 ng/ml

Comments on Substantial Equivalence: Both the proposed Dade Behring Dimension® Total Triiodothyronine (T3) Calibrator (RC414) and the existing Opus Total T3 calibrator are *in vitro* diagnostic products intended for calibrating T3 assays.

Conclusion: The Dimension® Total Triiodothyronine (T3) Calibrator (RC414) is substantially equivalent to the Opus Total T3 Calibrators based on the comparison discussed above.

Lorraine Piestrak

Lorraine Piestrak
Regulatory Affairs and Compliance Manager
August 29, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Larraine Piestrak
Regulatory Affairs and Compliance Manager
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Newark, Delaware 19714

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Re: k032697
Trade/Device Name: Dimension® Total Triiodothyronine Calibrator (RC414)
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIS
Dated: August 29, 2003
Received: September 2, 2003

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name: Dimension® Total Triiodothyronine Calibrator (RC414)

Indications for Use:

The Dimension® Total Triiodothyronine (T3) Calibrator (RC414) is intended for use in the calibration of the Total Triiodothyronine (T3) method on the Dimension® clinical chemistry system with the Heterogeneous Immunoassay Module.

Lorraine Piestrak
Regulatory Affairs and
Compliance Manager

August 29, 2003

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k032697