AUG 1 5 1996

510(k) Summary

K962508

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: LeeAnn Chambers

Date Prepared: June 24, 1996

2) Device name

Proprietary name: Elecsys T3

Common name: Total triiodothyronine test system

3) Predicate device

We claim substantial equivalence to the Enzymun-Test® T3.

4) Device Description

The Elecsys® T3 employs a competitive test principle with polyclonal antibodies directed against T3 and with streptavidin microparticles and electrochemiluminescence detection.

Total duration of assay: 18 minutes.

- 1st Incubation: Sample (30 µl) and specific anti-T3 antibodies labeled with a ruthenium complex together with ANS to release T3 from serum.
- 2nd Incubation: After the addition of streptavidin-coated microparticles and biotinylated T3, the still-free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the solid phase via interaction of biotin and streptavidin.

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4) Device Description (cont.)

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.

5) Intended use

For the *in vitro* quantitative determination of total triiodothyronine (T3) in human serum and plasma.

5) Indications for use

Triiodothyronine (T3) is the hormone principally responsible for the development of the effects of the thyroid hormones on the various target organs.

T3 (3,5,3' Triiodothyronine) is mainly formed extra-thyroidally, particularly in the liver, by enzymatic 5'-deiodination of T4. Accordingly, the T3 concentration in serum is more a reflection of the functional state of the peripheral tissue than the secretory performance of the thyroid gland.

A reduction in the conversion of T4 to T3 results in a fall in the T3 concentration. It occurs under the influence of medications such as propanolol, glucocorticoids or amiodarone and in severe non-thyroidal general diseases - "non-thyroidal illness" (NTI) - and is referred to as the "low T3 syndrome." Like T4, over 99% of T3 is bound to transport proteins, but its affinity to them is around 10-fold lower.[1-3,7]

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5) Indications for use

The determination of T3 is utilized in the diagnosis of T3-hyperthyroidism, the detection of early stages of hyperthyroidism and for indicating a diagnosis of thyrotoxicosis factitia.[4-6]

References

1 Wheeler MH, Lazarus JH. Diseases of the Thyroid. Chapman and Hall Medical. London Glasgow Weinheim New York Tokyo Melbourne Madras 1994;107-115.

2 Pfannenstiel P, Saller B. Schilddrüsenkrankheiten Diagnose und Therapie. Berliner Medizinische Verlagsanstalt GmbH 1995; 2:30-32,60-62.

3 Fisher DA. Physiological variations in thyroid hormones physiological and pathophysiological considerations. Clinical Chemistry 1996;42:135-139.

4 Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. Clinical Chemistry 1996;42:155-159.

5 Surks MI, Chopra IJ, Mariash CN, Nicoloff JT, Solomon DH. American Thyroid Association guidelines for use of laboratory tests in thyroid disorders. JAMA 1990;63:1529-1532.

6 Becker DV, Bigos ST, Gaitan E, Morris JC, Rallison ML, Spencer CA, et at. Optimal use of blood tests for assessment of thyroid function (letter). JAMA 1993. 269:273.

7. Wild D. The Immunoassay Handbook. Stockton Press 1994; 338.

6) Comparison to predicate device

The Boehringer Mannheim Elecsys T3 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test® T3.

Similarities:

- Intended use: immunoassay for the *in vitro* quantitative determination of Total Triiodothyronine (T3)
- Competitive test principle
- Sample type: serum and plasma
- Antibody: sheep anti-T3 polyclonal
- Capture principle: streptavidin / biotin

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6) Comparison to predicate device (cont.)

Differences:

Feature	Elecsys T3	Enzymun-Test T3
Reaction test principle	streptavidin microparticles and electrochemiluminescence technology	streptavidin-coated tubes and enzyme immunoassay technology
Sample volume	30 µl	100 µl
Instrument required	Elecsys 2010	ES 300
Calibration	a two point calibration renewal is recommended every 7 days or 1 month if the same reagent lot is used and the reagent pack is consumed within 7 days	a full calibration curve run is recommended every 2 weeks

Performance Characteristics:

Feature	Elecsys T3					Enzymun-Test® T3		
Precision:	NCCLS (modified) (EP5-T2):					Modified NCCLS "Midi" (EP3-T)		
Sample	PC U1	PC U2	HS1	HS2	HS3	1	2	3
N	60	60	60	60	60	118	120	117
Mean (nmol/l)	2.12	6.31	1.22	2.87	5.09	0.95	2.56	4.26
wi/in run % CV	4.1	3.5	3.6	4.2	5.3	2.9	1.6	1.7
total run % CV	4.8	4.1	5.4	4.7	5.4	4.7	2.2	2.8
Sensitivity	Lower Detection Limit: 0.3 nmol/l 0.19 ng/ml					Lower Detection Limit: 0.46 nmol/l 0.3 ng/ml		
Assay range (LDL to high std.)	0.3 - 10.00 nmol/l 0.19 - 6.51 ng/ml					0.46 - 9.22 nmol/l 0.3 - 6.0 ng/ml		

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F. Substantial equivalence, (cont.) **Performance Characteristics:**

Method Comparison	vs. Enzymun-Test T3 (Cat. # 1360868) Least Squares: N = 300 y = - 0.35 + 1.18x r = 0.957 Passing/Bablok N = 300 y = -0.56 + 1.26x r = 0.957	vs. Enzymun-Test T3 (Cat. # 1135287) Least Squares: N = 55 y = 1.13x + 0.02 r = 0.994
Interfering substance: Hemoglobin Lipemia Bilirubin Biotin	No interference up to: 1 g/dl 1500 mg/dl 25 mg/dl 20 ng/ml	No interference up to: 1 g/dl 1250 mg/dl 65 mg/dl 50 ng/ml
Specificity D-T3 L-T4 D-T4 L-rT3 L-T2 3,3',5-tri-iodothyroacetic acid 3,3',5,5'-tetra-iodothyroacetic acid	% cross reaction 98.9 0.115 0.115 0.007 0.998 106.4 0.007	% cross reaction 100 0.16 0.07 0.04 1.0 7.5 0.01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 15 1996

LeeAnn Chambers, RAC
Program Manager, Regulatory Affairs
Boehringer Mannheim Corporation
Quality System & Compliance
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K962508
Elecsys T3
Regulatory Class: II
Product Code: CDP, JIS
Dated: July 25, 1996
Received: July 26, 1996

Dear Ms. Chambers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K-962508
Device Name: Elecsys® T3
Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K962508

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)