K062581

510(k) Summary

NOV 29 2006

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

1.	Submitter name, address, contact	Olympus America 3131 W Royal Lane Irving, TX 75063	
		Telephone: Fax:	(972) 556-9697 (972) 556-0365
		Contact Person:	David Davis
		Date Prepared:	October 6, 2006
2.	Device name	Proprietary Name:	Olympus TSH Reagent Olympus TSH Calibrator Olympus TSH Control Olympus AU3000i™ Immunoassay System
		Common Name:	TSH Reagent, Calibrator & Control Immunoassay Analyzer
		Classification Name:	Thyroid-Stimulating Hormone Test System, Calibrator, secondary Single (specified) analyte control (assayed and unassayed) Analyzer, Chemistry (Photometric, Discrete), For Clinical Use
3.	Predicate device	Reagent:	Roche Elecsys® TSH Assay (K961491)
		Calibrator:	Roche Elecsys® TSH CalSet (K060754)
		Control:	Roche Elecsys® PreciControl TSH (K962573)
		Analyzer:	Roche Elecsys® 2010 analyzer (K961481)

4. Device description	The Olympus TSH assay is a two-step paramagnetic particle enzyme immunoassay. It is based on the sandwich principle and used to quantitate TSH in serum/plasma. The Olympus TSH assay reagent and sample are added to the assay cuvette in the following sequence: 1. Samples are incubated first with a monoclonal anti-TSH antibody bound to paramagnetic particles. 2. After a washing step, a second monoclonal anti-TSH antibody conjugated with alkaline phosphatase is added. The TSH reacts with the paramagnetic particles and the conjugated antibody to form a sandwich complex. Washing steps remove the unbound material. 3. The chemiluminescent substrate is added to the assay cuvette and reacts with the bound alkaline phosphatase (ALP). Light generated by the reaction is measured by the luminometer. The light emission is proportional to the quantity of TSH in the sample. 4. Results are calculated from a pre-defined calibration curve. The Olympus AU3000i system automatically calculates the TSH concentration of each sample in mIU/L or µIU/mL.
5. Intended use	The Olympus thyroid stimulating hormone (TSH) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of TSH levels in human serum and plasma using the Olympus AU3000i™ Immunoassay System. Measurements of TSH produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The Olympus TSH Calibrator is used for calibrating the quantitative Olympus TSH Assay on the Olympus AU3000i Immunoassay System. The Olympus TSH Control is used for quality control of the Olympus TSH test system on the Olympus AU3000i Immunoassay System. The Olympus AU3000i Immunoassay System is a chemiluminescent discrete photometric chemistry analyzer for the quantitative determination of analytes in human serum and plasma.

6. Comparison to predicate device

The following tables compare the Olympus TSH Test System with the Roche Elecsys® TSH Test System.

Item	Similarities AU3000i with TSH	Roche Elecsys® TSH
Intended Use	Quantitative determination of thyroid stimulating hormone (TSH) levels in human serum/plasma	Immunoassay for the in vitro quantitative determination of thyrotropin in human serum and plasma.
Traceability	WHO	WHO
Detection/Operating Principle	Chemiluminescence	Chemiluminescence
Assay Methodology	Sandwich immunoassay	Sandwich immunoassay
Solid Phase	Micro-particle	Micro-particle
Sample Type	Serum and plasma	Serum and plasma
Antibody	Monoclonal anti-TSH mouse antibody	Monoclonal anti-TSH mouse antibody
Analyzer Reagents	On-board Storage Bar-coded (1-D & 2-D) reagent, calibrator & control Cap/septum for increased reagent stability and evaporation control	On-board Storage Bar-coded (1-D & 2-D) reagent, calibrator & control Cap/septum for increased reagent stability and evaporation control
Reagent, Calibrator and Control storage form	Liquid	Liquid
Calibration and Control Stability	Unopened • At 2-8°C up to the stated expiration date Opened • 28 days / 4 weeks at 2-8°C	Unopened • At 2-8°C up to the stated expiration date Opened • 28 days / 4 weeks at 2-8°C
Control levels and target concentration range	One Euthyroid/Hyperthyroid threshold	One Euthyroid/Hyperthyroid threshold
Control constituents	Single	Single
Control Matrix	Human serum with added antigen	Human serum with added antigen
Analyzer System	Fully automated Random access Computer controlled Stat capability	Fully automated Random access Computer controlled Stat capability
Analyzer/User Interface	Keyboard/touch screen control Colored touch screen monitor Stationary barcode scanners Graphical user interface On line help	Keyboard/touch screen control Colored touch screen monitor Stationary barcode scanners Graphical user interface On line help
Analyzer Consumables	Disposable reaction vessels Disposable sample tips	Disposable reaction vessels Disposable sample tips
Analyzer Sample Detection	Liquid Level Detection Clot Detection	Liquid Level Detection Clot Detection
Analyzer Host Interface	RS232C bidirectional	RS232C bidirectional

Differences		
Item	AU3000i with TSH	Roche Elecsys® TSH
Instrument Required	Olympus AU3000i™ Immunoassay System	Roche Elecsys and Modular analytics immunoassay analyzers.
Traceability	WHO 3rd IS 81/565	WHO 2nd IRP 80/558
Calibrator levels and target Concentration	One Cal: 13 µIU/mL	Two Cal 1: 0 µIU/mL Cal 2: 1.5 µIU/Ml
Solid phase binding principle	Direct coating	Biotin and streptavidin
Assay Range	0.001 – 130 µIU/mL	0.005 – 100 µIU/mL
Calibrator Matrix	Bovine serum human pituitary TSH	Horse serum with added recombinant TSH
Analyzer Sample Volume	10 – 100 µl	10 – 50 µl
Analyzer Reagent Positions	24 reagent positions 2 diluent/pretreatment positions	15 reagent positions 2 diluent/pretreatment positions
Analyzer Throughput	240 results/hour	88 results/hour

Performance Characteristics		
Item	AU3000i with TSH	Roche Elecsys® TSH
Precision	Sample Total CV% Low 2.9 Med 6.0 High 3.7	Sample Total CV% Low 8.7 Med 3.3 High 3.6
Functional Sensitivity Analytical Sensitivity	0.0013 µIU/mL 0.0002 µIU/mL	0.014 µIU/mL 0.005 µIU/mL
Measurable Range	0.001 – 130 µIU/mL	0.005 – 100.0 µIU/mL
Method Comparison (Passing Bablok)	Intercept-0.0046 Slope 0.935 R 0.9931	Intercept0.01 Slope 1.01 R 0.944
Applicable Interfering Substances	Bilirubin ≤ 10% @ 40 mg/dL Hemolysis ≤ 5% @ 5 g/L Lipemia ≤ 3% @ 10 g/L	Bilirubin ≤ 10% @ 41 mg/dL Hemolysis ≤ 10% @ 1 g/dL Lipemia ≤ 10% @ 1500 mg/dL
Specificity	LH No significant interference FSH No significant interference hGH Not Tested hCG Not Detected	LH No significant interference FSH No significant interference hGH Not Detected hCG Not Detected

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. David Davis
Manager, RA/QA
Olympus America, Inc.
3131 West Royal Lane
Irving, TX 75063

NOV 29 2006

Re: k062581
Trade/Device Name: Olympus TSH (thyroid stimulating hormone) Test System and Olympus AU3000i™ Immunoassay System
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JLW, JIS, JJX, JJE
Dated: August 28, 2006
Received: August 31, 2006

Dear Mr. Davis:

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): K062581

Device Name: Olympus TSH (thyroid stimulating hormone) Test System and Olympus AU3000i™ Immunoassay System

Indications for Use:

The Olympus thyroid stimulating hormone (TSH) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of TSH levels in human serum and plasma using the Olympus AU3000i™ Immunoassay System.

Measurements of TSH produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Olympus TSH Calibrator is used for calibrating the quantitative Olympus TSH Assay on the Olympus AU3000i Immunoassay System.

The Olympus TSH Control is used for quality control of the Olympus TSH test system on the Olympus AU3000i Immunoassay System.

The Olympus AU3000i Immunoassay System is a chemiluminescent discrete photometric chemistry analyzer for the quantitative determination of analytes in human serum and plasma.

Prescription Use _____x_____ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K062581