Triglyceride 510(k)

K063804

Section 2 - 510(k) Summary

- As required by 21 CFR 807.87 (h) –

MAR 23 2007

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:	972-619-4710 972-556-0365
		Contact Person:	Bev Harding
		Date Prepared:	December 18, 2006
2.	Device name	Proprietary Name:	Olympus Triglyceride Reagent
		Common Name:	Triglyceride Reagent
		Classification Name:	Triglyceride Test System,
3.	Predicate device	Reagent:	Olympus Triglyceride OSR6x33 (K961274)
4.	Device description	This Olympus Triglyceride procedure is based on a series of coupled enzymatic reactions. The triglycerides in the sample are hydrolyzed by a combination of microbial lipases to give glycerol and fatty acids. The glycerol is phosphorylated by adenosine triphosphate (ATP) in the presence of glycerol kinase (GK) to produce glycerol-3-phosphate. The glycerol-3-phosphate is oxidized by molecular oxygen in the presence of GPO (glycerol phosphate oxidase) to produce hydrogen peroxide (H_2O_2) and dihydroxyacetone phosphate. The formed H_2O_2 reacts with 4-aminophenazone and N,N-bis(4-sulfobutyl)-3,5-dimethylaniline, disodium salt (MADB) in the presence of peroxidase (POD) to produce a chromophore, which is read at 660/800nm. The increase in absorbance at 660/800 nm is proportional to the triglyceride content of the sample.	
		$\text{Triglycerides} + 3\ H_2O \xrightarrow{\text{Lipase}} \text{Glycerol} + 3\ \text{Fatty Acids}$	
		$\text{Glycerol} + \text{ATP} \xrightarrow{GK, Mg^{2+}} \text{Glycerol-3-phosphate} + \text{ADP}$	
		$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} H_2O_2 + \text{Dihydroxyacetone phosphate}$	
		$2\ H_2O_2 + \text{MADB} + \text{4AAP} \xrightarrow{\text{Peroxidase}} \text{Blue Dye} + OH^- + H_2O$	
5.	Intended use	System reagent for the quantitative determination of Triglyceride concentrations in human serum and plasma on OLYMPUS analyzers.	

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6. The following Tables compare the new Olympus Triglyceride OSR6x118 with the Olympus Triglyceride OSR6x33

Similarities		
Item	New Olympus Triglyceride	Predicate
Measurement	Quantitative	Same
Chemical reaction	Enzymatic GPO methodology with Trinder indicator system	Same
Sample dilution	Not required	Same
Reagent Materials	Lipoprotein Lipase and coupling enzymes and co-factors	Same
Traceability	College of American Pathology (CAP) Serum Lipid (RM016) # 2	Same
Reagent storage form	Liquid ready to use	Same
Reagent On Board Stability	30 days on board	Same
Calibration	Single Point	Same
Calibration Stability	30 days	Same
Quality Controls	2 Levels	Same

Differences		
Item	New Olympus Triglyceride	Predicate
Intended Use	System reagent for the quantitative determination of Triglyceride concentrations in human serum and plasma on OLYMPUS analyzers	System reagent for the quantitative determination of Triglyceride concentrations in human serum on OLYMPUS analyzers
Catalogue Number	OSR6x118	OSR6x33
Specimen Type	Serum and Plasma	Serum
Indicator	N,N-bis(4-sulfobutyl)-3,5-dimethylaniline, disodium salt (MADB)	4-chlorophenol
Methodology	Enzymatic endpoint at approximately 660nm	Enzymatic endpoint at approximately 520nm
Expected Values	Adults: 48 - 352mg/dL <u>Triglyceride</u> — <u>Risk Classification</u> <150 mg/dL — Normal 150-199 mg/dL — Borderline High 200-499 mg/dL — High ≥500 mg/dL — Very High	Adults: 48 -352mg/dL

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Performance Characteristics		
Item	New Olympus Triglyceride	Predicate
Precision AU400/400e	Sample Total CV% 1 2.58 2 2.54 3 2.41	Sample Total CV% 1 1.21 2 1.67 3 1.37
Precision AU600/640/640e	Sample Total CV% 1 1.65 2 1.41 3 1.46	AU600 Sample Total CV% 1 1.83 2 1.58 3 2.80 4 1.13 AU640/640e Sample Total CV% 1 1.00 2 1.00
Precision AU2700/5400	Sample Total CV% 1 2.00 2 1.72 3 1.78	Sample Total CV% 1 2.50 2 2.00 3 1.50 4 1.20
Assay Range	10 - 1000 mg/dL	10 - 1000 mg/dL
Method Comparison	Intercept -0.871 Slope 1.011 R 1.000	Intercept 3.2 Slope 1.010 R 0.999
Interfering Substances	AU400/400e/600/640/640e/2700/5400 Ascorbate ≤ 5% up to 20 mg/dL Bilirubin ≤ 3% up to 40 mg/dL Hemolysis ≤ 3% up to 500 mg/dL	AU400/400e Ascorbate ≤ 2% up to 20mg/dL Bilirubin ≤ 10% up to 20 mg/dL Hemolysis ≤ 8% up to 500 mg/dL AU600/640/640e Ascorbate ≤ 1% up to 20mg/dL Bilirubin ≤ 10% up to 32 mg/dL Hemolysis ≤ 7% up to 500 mg/dL AU2700/5400 Ascorbate ≤ 2% up to 20mg/dL Bilirubin ≤ 10% up to 16 mg/dL Hemolysis ≤ 8% up to 500 mg/dL

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Olympus America, Inc.
c/o Ms. Bev Harding
3131 West Royal Lane
Irving, TX 75063-3104

MAR 23 2007

Re: k063804
Trade/Device Name: Olympus Triglyceride Test System
Regulation Number: 21 CFR§ 862.1705
Regulation Name: Triglyceride test system.
Regulatory Class: Class I meets limitations of exemptions, 21 CFR 862.9 (c) (4)
Product Code: CDT
Dated: March 16, 2007
Received: March 19, 2007

Dear Ms. Harding:

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

Indication For Use

510(k) Number (if known): K063804

Device Name: Olympus Triglyceride Test System.

Indications for Use:

System reagent for the quantitative determination of Triglyceride concentrations in human serum and plasma on OLYMPUS analyzers

Measurements of triglyceride are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders, and in the assessment of risk factors for atherosclerosis and coronary artery disease.

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

K063804