DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 8 2002

Mr. Michael Campbell
Manager, Regulatory Affairs/Quality Assurance
Olympus America Inc
Diagnostic Systems Group
3131West Royal Lane
Irving Texas 75063-3104

Re: k014032
Trade/Device Name: Olympus LDL Cholesterol Test System
Regulation Number: 21 CFR 862.1475; 21 CFR 862.1150
Regulation Name: Lipoprotein test system; Calibrator
Regulatory Class: Class I; Class II
Product Code: LBS; JIT
Dated: January 18, 2002
Received: January 22, 2002

Dear Mr. Campbell:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K014032

Device Name: **Olympus LDL Cholesterol Test System**
Contents:
Olympus LDL Cholesterol Reagent
Olympus LDL Cholesterol Calibrator
Olympus HDL/LDL Cholesterol Control

Indications for Use:

The Olympus LDL Cholesterol Test System contains LDL Cholesterol Reagent, LDL Cholesterol Calibrator, and Assayed HDL/LDL Cholesterol Control materials intended for use on the Olympus Family of Clinical Chemistry Analyzers for the quantitative determination of LDL Cholesterol concentrations in human serum and plasma.

The Olympus LDL Cholesterol Calibrator is a lyophilized human serum intended to provide an LDL concentration of known value for use in calibration of the Olympus LDL Cholesterol Reagent used on the Olympus family of Clinical Chemistry Analyzers.

The Olympus HDL/LDL Cholesterol Control consists of lyophilized human sera. These assayed control sera a designed to monitor the recovery and precision of the Olympus LDL Cholesterol Reagent used on the Olympus family of Clinical Chemistry Analyzers.

LDL Cholesterol levels play a causal role in the development of coronary artery disease and is used for the measurement of the LDL Cholesterol concentration in serum and plasma.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014032

(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) (Optional Format 1-2-96)