DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 21 2007

OLYMPUS Life & Material Science
Europa GMBH (Irish Branch)
c/o Ms. Stephanie G. Schwartz
Regulatory Affairs Quality Assurance Manager
Lismeehan, O'Callaghans Mills Co.
Clare, Ireland

Re: k070708
Trade/Device Name: Olympus FT4 Free thyroxine (catalogue no. OSR210102)
Olympus T4 Total thyroxine (catalogue no. OSR210104)
Regulation Number: 21 CFR §862.1695
Regulation Name: Free Thyroxine test system.
Regulatory Class: Class II
Product Code: CEC, CDX
Dated: July 20, 2007
Received: July 23, 2007

Dear Mr. Byrne:

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): K070708

Device Name: Olympus fT4 Test System.

Indications for Use:

The Olympus fT4 assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of free thyroxine levels in human serum/plasma using the Olympus AU3000i™ Immunoassay System. Measurements obtained by this device are used in the diagnosis and treatment of thyroid disease. For *in vitro* diagnostic use only.

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

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional Format 1-2-96) K070708

Indication For Use

510(k) Number (if known): K070708

Device Name: Olympus T4 Test System.

Indications for Use:

The Olympus T4 assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total thyroxine levels in human serum/plasma using the Olympus AU3000i™ Immunoassay System. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases. For *in vitro* diagnostic use only.

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)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K070708