



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 18 2009

Olympus America Inc.
c/o Ms. Stephanie G. Donnelly
Regulatory Affairs/Quality Assurance Manager
Olympus Life Science Research Europa GmbH
Lisheehan, O'Callaghan's Mills
Co. Clare, Ireland

Re: k081615

Trade/Device Name: Olympus Carcinoembryonic antigen (CEA)
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor- associated antigen immunological test system
Regulatory Class: II
Product Code: DHX, JJX, JIT
Dated: February 25, 2009
Received: March 5, 2009

Dear Ms. Donnelly:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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

Page 2- Ms. Stephanie G Donnelly

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 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 advice for your device on the labeling regulation, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240- 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For question regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR), please contact the Division of Surveillance Systems at 240-276-3464. 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 <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and
Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081615

Device Name: The Olympus Carcinoembryonic antigen (CEA) Test System

Indications For Use:

The Olympus CEA assay is a paramagnetic particle (Dynabeads®), chemiluminescent immunoassay for the quantitative determination of carcinoembryonic antigen levels in human serum and lithium heparin plasma using the Olympus AU3000i Immunoassay System. The Olympus CEA assay is indicated for serial measurement of CEA as an aid in the management (monitoring) of colorectal cancer patients. These CEA values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is made. For *in vitro* diagnostic use only.

The Olympus CEA Calibrator is for calibrating the quantitative Olympus CEA assay on the Olympus AU3000i Immunoassay System.

The Olympus CEA Control is used for quality control of the Olympus CEA assay on the Olympus AU3000i Immunoassay System.

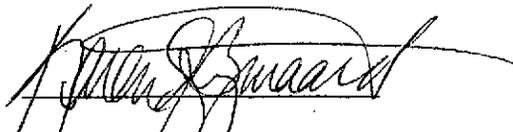
Prescription Use
Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

 K081615
510(k)

Page 1 of _____