



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN - 6 2006

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

Re: k060201

Trade/Device Name: Olympus RF Latex Reagent and Olympus RF Latex Calibrator  
Regulation Number: 21 CFR 866.5775  
Regulation Name: Rheumatoid Factor Immunological Test System  
Regulatory Class: Class II  
Product Code: DHR, JIT  
Dated: January 20, 2006  
Received: January 26, 2006

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 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 Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

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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), please contact the Office of Compliance 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,

*Maria Chan for  
Dr Robert Becker*

Robert L. Becker, Jr., M.D., 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): K060201

Device Name: **Olympus RF Latex**

Indications for Use:

Olympus RF Latex System Reagent for the quantitative determination of Rheumatoid Factor (RF) in human serum and plasma on OLYMPUS Analyzers. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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IF NEEDED)

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

*maria chan*  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

    K060201

## Indications for Use

510(k) Number (if known): K060201

Device Name: **Olympus RF Latex Calibrator**

Indications for Use:

The Olympus RF Latex Calibrator is a liquid human serum based matrix calibrator intended to be used with the Olympus RF Latex reagent OSR61105 for the quantitative determination of Rheumatoid Factor (RF) on Olympus analyzers.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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

*Maria Chan*  
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Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

*K060201*  
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