



JUN 25 2001

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: 510(k) Number: K011720
Trade/Device Name: Olympus AU5400 Clinical Chemistry Analyzer

Regulation Number: 862.2160 862.1030 862.1035 862.1050 866.5420 866.5130
862.1070 866.3720 862.1475 862.1475 862.1100 866.5630
862.1110 862.1110 862.1145 862.1160 862.1170 862.1175
866.5240 866.5240 866.5270 862.1215 862.1215 862.1225
866.5340 862.1360 862.1345 866.5460 862.1475 866.5510
866.5510 866.5510 862.1410 862.1415 862.1440 862.1465
862.1495 866.5040 866.5680 862.1580 862.1600 866.5060
862.1635 866.5775 862.1665 866.5880 862.1705 862.1770
862.1775

Regulatory Class: II
Product Code: CIX CJE DEM JFJ GTQ JHN CIT JZG CIG CIG CIC CHS CGZ CZW
DBI DCN CGS JLB CGX DBF CFR DAD CFQ CFQ CFJ JIR
DDR
CEO CEM CEK DHR JGS DDD CDQ

Regulatory Class: I
Product Code: JJE CKA LKL JHN JHN CHH JQB LBS JIY JMO CDT JGJ DDS
CDT CDO

Dated: June 1, 2001
Received: June 4, 2001

Dear Mr. Campbell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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. 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.

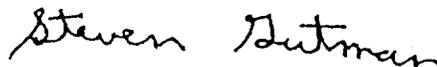
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known): K011720

Device Name: Olympus AU5400 Clinical Chemistry Analyzer

Indications for Use:

The Olympus AU5400 Clinical Chemistry Analyzer is a fully automated photometric analyzer intended for clinical laboratory use. Applications include colorimetric, turbidimetric, latex agglutination, and homogeneous enzyme immunoassay.

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011720

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

Concurrence of ~~CDRH~~, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)