

K974456

SECTION 3

MAY 1 1998

CMVgen - 510(k) SUMMARY  
(Summary of Safety and Effectiveness)

**Submitted by:**

Carol Marble  
Regulatory Affairs Engineer  
Instrumentation Laboratory Company  
113 Hartwell Avenue  
Lexington, MA 02173  
Phone: (781) 861-4467  
Fax: (781) 861-4464

**Contact Persons:**

Carol Marble  
Phone: (781) 861-4467

**Summary Prepared:**

November 24, 1997 (Revised on February 23, 1998)

**Name of the device:**

CMVgen

**Classification name(s):**

866.3175 Cytomegalovirus serological reagents Class II  
83LJO Antigen, IHA, Cytomegalovirus

**Identification of predicate device(s):**

CMVscan K841520

**Description of the device/intended use(s):**

CMVgen is an *in vitro* diagnostic, rapid latex particle agglutination test for the qualitative and semiquantitative determination of total antibodies (IgG and IgM) to cytomegalovirus (CMV) in human serum or plasma (EDTA) to determine prior exposure to cytomegalovirus. This product is not FDA cleared for use in screening blood or plasma (EDTA) donors.

**Statement of How the Technological Characteristics of the Device compare to the Predicate Device:**

CMVgen uses the same test principle (passive latex agglutination) as the predicate CMVscan and is substantially equivalent in performance, intended use, and safety and effectiveness with the exception that CMVscan is labeled for use to screen donor specimens.

**Summary of Performance Data:**

In a method comparison study performed at UMMC Clinical Microbiology Laboratories (Massachusetts) evaluating 165 serum samples, the sensitivity of CMVgen as compared to a commercially available total antibody test was 97.5%. In a separate study performed at Cambridge University (U.K.) evaluating 131 serum samples (ninety of which were collected from 31 organ transplant recipients who had experienced either a primary CMV infection or a reactivation of CMV post-transplant), the sensitivity of CMVgen as compared to a commercially available IgG EIA test was 91.1%.

In a reproducibility study, panels of 10 serum and plasma samples were tested on 3 consecutive days using the semiquantitative procedure for CMVgen. The results, as defined by the ability to give agreement to within one 2-fold dilution on the replicates, indicated 100% reproducibility.



MAY 1 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Carol Marble  
Senior Regulatory Affairs Specialist  
Instrumentation Laboratory Company  
113 Hartwell Avenue  
Lexington, MA 02173-3190

Re: K974456  
Trade Name: CMVgen  
Regulatory Class: II  
Product Code: LJO  
Dated: February 23, 1998  
Received: February 24, 1998

Dear Ms. Marble:

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 (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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

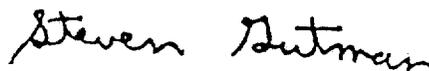
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

Enclosure

## Indications for Use Statement

510(k) Number (if known): \_\_\_\_\_

Device Name: CMVgen

### Indications for Use:

CMVgen is an *in vitro* diagnostic, rapid latex particle agglutination test for the qualitative and semiquantitative determination of total antibodies (IgG and IgM) to cytomegalovirus (CMV) in human serum or plasma to determine prior exposure to cytomegalovirus.

This assay has not been FDA cleared for use in screening blood or plasma donors.

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K974456

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.019)

OR Over-The-Counter Use \_\_\_\_\_