JUL 12 1999

K991650

11. 510(k) SUMMARY OF INFORMATION RESPECTING SAFETY AND EFFECTIVENESS

A. Name and Address of Submitter

Company Name and Address:	Biotest Diagnostics Corporation 66 Ford Road, Suite 131 Denville, NJ 07834
Telephone:	609-397-8511
FAX:	609-397-8224
Contact Person:	Patricia E. Bonness

B. Device Names

Proprietary Name:	CMV Brite™ Turbo Kit
Common Name:	Cytomegalovirus Antigen Detection
Classification Name:	Cytomegalovirus serological reagents

C. Legally Marketed Device

CMV Brite™ Test Kit (K951550)

D. Device Description

The CMV antigenemia assay has been developed using a cocktail of two monoclonal antibodies (C10/C11) directed against CMV lower matrix protein pp65[6]. The assay uses the C10/C11 cocktail in an indirect immunofluorescence staining of cytospin preparations of peripheral blood leukocytes. The CMV Brite™ Turbo antigenemia assay is completed within two hours of blood collection which saves time and means a rapid answer for the clinician. The CMV Brite™ Turbo method consists of:

a. Direct lysis of peripheral blood erythrocytes
b. Preparation of cytospin slides
c. Fixation and permeabilization
d. Indirect immunofluorescence staining using monoclonal antibodies directed against CMV pp65 protein
e. Reading and evaluation of results

The first step in the CMV Brite™ Turbo method involves direct lysis of the peripheral blood erythrocytes[22]. Following lysis the leukocytes are cytocentrifuged onto a slide, fixed and permeabilized to allow subsequent detection of CMV pp65 antigen. The presence of the CMV pp65 antigen is detected by the C10/C11 antibody cocktail and visualized by means of a specific secondary FITC-labeled antibody. CMV antigen-positive leukocytes exhibit homogeneous yellow-green polylobate nuclear staining when observed using a fluorescence microscope. The number of CMV antigen-positive cells are counted per duplicate stain.

The whole procedure can be performed in approximately 2 hours. The total analysis time has been shortened by performing direct erythrocyte lysis on whole blood and avoiding dextran sedimentation. Further time has been saved by shortening individual steps in the protocol so that the whole CMV antigenemia procedure has been reduced in time by more than 50%.

E. Intended Use

The CMV Brite™ Turbo Kit is intended for the qualitative detection of Cytomegalovirus (CMV) lower matrix protein pp65 by indirect immunofluorescence using microscopy in isolated peripheral blood leukocytes obtained from ethylenediaminetetraacetic acid (EDTA) or heparin anticoagulated human peripheral blood. The detection of CMV pp65 in human perpheral blood cells aids in the diagnosis of acute or reactivated CMV infection. This product is not FDA cleared (approved) for use in testing (i.e., screening) of blood or plasma donors.

F. Comparison with Predicate Device

A summary comparison of the features of the CMV Brite™ Turbo Kit and CMV Brite™ Test Kit is provided in Table 1 on the following page:

Table 1

Feature Comparison of the CMV Brite™ and CMV Brite™ Turbo Tests

	CMV Brite™	CMV Brite™ Turbo
Intended Use	Detection of CMV protein pp65 in peripheral leukocytes	Detection of CMV protein pp65 in peripheral leukocytes
Monoclonal Antibodies	Clones C10 and C11	Clones C10 and C11
Assay Method	Immunofluorescence Staining	Immunofluorescence Staining
Specimen: Type	Heparin or EDTA	Heparin or EDTA
Minimum vol	5 - 7 ml	3 - 5 ml
Preparation of Leukocyte Suspension	Dextran sedimentation and lysis of red cells with NH_4Cl	Direct lysis of red cells with NH_4Cl
	Centrifugation: 10 min at 300 xg	Centrifugation: 2 min at 1000 xg
Cell Count Required (cells/ml)	1.5×10^6	2×10^6
Affixing Method	Cytospin Centrifugation	Cytospin Centrifugation
Fixation Time	10 minutes	5 minutes
Permeabilization Time	5 minutes	1 minute
Staining	0.002% Evans Blue	0.00075% Evans Blue
Incubation Time	30 minutes	20 minutes
Microscope	Immunofluorescence	Immunofluorescence
Controls	Positive & negative control slide (20)	Positive & negative control slide (5)
	Leukocytes & SF9 Insect cells	Leukocytes & SF9 Insect cells
Sensitivity	91.0%	87.4%
Specificity	99.5%	98.8%
Positive Predictive Value	98.9%	92.4%
Negative Predictive Value	95.7%	97.9%
Kit Size	100 test	110 tests
Total Assay Time	5 hours	2 hours

G. Performance Data

The performance characteristics of the CMV Brite™ Turbo Kit are the same as those established for the CMV Brite™ Test Kit.

H. Conclusions Drawn from the Studies

The conclusions drawn from the design control and validation studies demonstrate that the CMV Brite™ Turbo Kit is as safe, effective, and performs as well as the legally marketed device to which equivalence is claimed, the CMV Brite™ Test Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Patricia E. Bonness
Official Correspondent
Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, New Jersey 07834

Re: K991650
Trade Name: CMV Brite™ Turbo Kit
Regulatory Class: II
Product Code: LIN
Dated: June 28, 1999
Received: July 1, 1999

Dear Ms. Bonness:

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.

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 Gutman

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

510(k) Number (if known): K991650

Device Name: CMV Brite™ Turbo Kit

Indications For Use:

The CMV Brite™ Turbo Kit is intended for use in the qualitative detection of Cytomegalovirus (CMV) lower matrix protein pp65 by indirect immunofluorescence using microscopy in isolated peripheral blood leukocytes obtained from ethylenediaminetreaacetic acid (EDTA) or heparin anticoagulated human peripheral blood. The detection of CMV pp65 in human peripheral blood cells aids in the diagnosis of acute or reactivated CMV infection. This product is not FDA cleared (approved) for use in testing (i.e., screening) of 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)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991650

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)