K992587

DEC 22 1999

510k Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Applicant Information:

Date Prepared:	July 20, 1999
Name:	Stellar Bio Systems, Inc.
Address:	9075 Guilford Road Columbia, MD 21046
Contact Person:	John Brewer
PhoneNumber.	410-381-8550
Fax Number.	410-381-8984

Device Information:

Trade Name:	Indirect Fluorescence Assay for Epstein-Barr Virus Early Antigen (EBV-EA) IgG Antibody
Common Name:	EBV-EA IgG IFA Test
Classification Name:	EBV-EA IgG Serological Reagent

Equivalent Device: IFA

Device Description: The Epstein-Barr Virus Early Antigen (EBV-EA) IgG IFA is an Indirect Fluorescence Assay (IFA) for the detection of IgG antibodies to EBV-EA in human serum.

Intended Use: The Stellar Bio Systems' Indirect Fluorescence Assay (IFA) for Epstein-Barr Virus Early Antigen (EBV-EA) IgG Antibody is intended for the qualitative and semi-quantitative detection of IgG (Immunoglobulin G) antibody to the early antigen complex of the Epstein-Barr Virus in human serum. The test detects IgG antibodies to EBV antigens in chemically induced Raji cells. The EBV-EA IFA Test Kit should be used in combination with other Epstein-Barr serologies [Viral Capsid Antigen (VCA) IgG and IgM, Epstein-Barr Nuclear Antigen (EBNA), and heterophile antibody] as an aid in the diagnosis of infectious mononucleosis (IM).

Principle of Procedure:

Stellar Bio Systems' fluorescent antibody assays use the indirect method of antibody detection and titer determination. Diluted patient serum samples are applied to fixed antigens provided on paint delineated wells on glass microscope slides. During a 30 minute incubation, antibody specific for EA forms an antigen/antibody complex with the fixed antigens. In a brief washing step, nonspecific antibody and other unreacted serum proteins are eliminated. Fluorescein-conjugated goat anti-human IgG is then applied to the wells of the glass slide. The anti-IgG conjugate combines with human IgG, if present, during a 30 minute incubation. After a brief wash to remove unreacted conjugate, the slides are viewed by fluorescence microscopy. A positive antibody reaction is denoted by bright green fluorescence at the antigen sites.

Performance Characteristics

1. **Relative Sensitivity and Specificity** - The Stellar EBV-EA IFA kit was evaluated relative to a commercially available EBV-EA IFA. The samples were selected frozen retrospective sera tested at a commercial clinical laboratory. The acute sera were selected by being positive in a heterophile assay. The seronegative sera were selected by being negative for VCA G and EBNA G by ELISA. The seropositive sera were selected by being positive for VCA G and EBNA G by ELISA.. The data in Table 1 summarizes the data.

Table 1
Relative Sensitivity and Specificity of the Stellar EBV-EA IFA Kit
Relative to Alternate IFA

		Stellar EBV-EA IFA Positive	Negative	Total
	Positive	42	1	43
Alternate IFA	Negative	6*	26	32
	Total	48	27	75

	95% Confidence Interval
Overall Agreement = 68/75 = 90.7%	81.7% - 96.2%

*The 6 Stellar positive/Alternate IFA negative samples were acute sera determined by ELISA VCA IgM.

Please be advised that 'relative' refers to the comparison of this assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison assay's accuracy to predict disease.

Since the above studies were performed on a pre-selected retrospective population no calculations for the assay's positive and negative predictive value may be done or inferred.

The above sera were categorized relative to their serological status to EBV. The following table illustrates the results:

	Acute VCA IgM (+) EBNA (-)	**Seropositive** VCA IgG (+) EBNA (+) VCA IgM (-)	**Seronegative** VCA IgG (-) VCA IgM (-) EBNA (-)
EBV EA IgG IFA			
Positive	20	25	3
Negative	10	7	10
Total	30	32	13

2. **Titer Agreement:** 25 positive sera were serially two-fold diluted and the endpoint titer was determined on the Stellar EBV-EA IFA and a commercially available EBV-EA IFA. The endpoint titer results are as follows.

Identical Titer	9/25
± one, two-fold dilution	12/25
± two, two-fold dilutions	4/25

3. **Reproducibility:** Three positive sera with various titers (1:80,1:160, 1:640) and one negative sera were serially diluted and assayed five times each on three different assays at three different sites. 131/180 of the end point titers were identical. 49/180 of the end point titers was within ± one, two-fold dilution.

4. **Specificity**
The following sera that were positive for IgG antibodies to CMV, VZV, HSV 1, HSV 2, HHV 6 and HHV 8 by IFA were found to be negative for EBV-EA IFA, indicating a lack of cross-reactivity to these viruses.

Sample	EA IFA Result
CMV +	-
VZV +	-
HSV 1&2 +	-
HSV 1&2 +	-
HSV 1&2 +	-
HSV 1&2 +	-
HHV 6+	-
HHV 6+	-
HHV 8+	-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 1999

Mr. John Brewer
President
Stellar Bio Systems, Inc.
9075 Guilford Road
Columbia, Maryland 21046

Re: K992587
Trade Name: Indirect Fluorescence Assay (IFA) for Epstein-Barr Virus Early Antigen (EBV-EA) IgG Antibody
Regulatory Class: I
Product Code: LSE
Dated: October 29, 1999
Received: October 29, 1999

Dear Mr. Brewer:

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): K992587

Device Name: Indirect Fluorescence Assay (IFA) for Epstein-Barr Virus Early Antigen (EBV-EA) IgG Antibody

Indications For Use: **The Stellar Bio Systems' Indirect Fluorescence Assay (IFA) for Epstein-Barr Early Antigen (EBV-EA) IgG Antibody is intended for the qualitative and semi-quantitative detection of IgG (Immunoglobulin G) antibody to the early antigen complex of the Epstein-Barr Virus in human serum. The test detects IgG antibodies to both the diffuse (D) and restricted (R) components of the EBV early antigen complex. The EBV-EA IFA Test Kit should be used in combination with other Epstein-Barr serologies (Viral Capsid Antigen (VCA) IgG and IgM, Epstein-Barr Nuclear Antigen (EBNA), and heterophile antibody) as an aid in the diagnosis of infectious mononucleosis (IM).**

(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 K992587

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)