4/21/99

K990916

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:	March 12, 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 Anti-native DNA (nDNA) IgG Antibody
Common Name:	nDNA IgG IFA Test
Classification Name:	nDNA IgG Serological Reagent

uivalent Device:
-ous DNA IFA

Device Description: The nDNA IgG IFA is an Indirect Fluorescence Assay (IFA) for the detection of IgG antibodies to nDNA antigen in human serum.

Intended Use: The Stellar Bio Systems' Indirect Fluorescence Assay (IFA) for Anti-native DNA (nDNA) IgG Antibody is intended for the qualitative and semi-quantitative detection of IgG (Immunoglobulin G) antibody to nDNA in human serum. Detection of nDNA IgG antibody in humans can be used as an aid in the diagnosis of systemic lupus erythematosus (SLE).

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 nDNA antigens 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 nDNA IFA kit was evaluated relative to a commercially available nDNA IFA. The samples were frozen retrospective sera. Fifty sera were from patients diagnosed with SLE. Ninety-nine sera were from normals with various ages, gender, and geographical areas. The data in Table 1 summarizes the data.

Table 1
Relative Sensitivity and Specificity of the Stellar nDNA IFA Kit Relative to Alternate IFA

		Stellar nDNA IFA		
		Positive	Negative	Total
Alternate IFA	Positive	25	1	26
	Negative	1	122	123
	Total	26	123	149

	95% Confidence Interval
Relative Sensitivity = 25/26 = 96.2%	80.4% - 99.9%
Relative Specificity = 122/123 = 99.2%	95.6% - 100%
Relative Agreement = 147/149 = 98.7%	95.2% - 99.8%

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.

2. **Titer Agreement:** 20 positive sera were serially two-fold diluted and the endpoint titer was determined on the Stellar nDNA IFA and a commercially available nDNA IFA. The endpoint titer results are as follows.

Identical Titer	11/20
± one, two-fold dilution	7/20
± two, two-fold dilutions	2/20

3. Reproducibility: Three positive with various titers (1:20, 1:160, 1:640) and one negative sera were serially diluted and assayed three times each on three different assays. 31/36 of the end point titers were identical. 5/36 of the end point titers were within ± one, two-fold dilution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1999

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

Re: K990916
Trade Name: Indirect Fluorescence Assay for Anti-native DNA (nDNA) IgG Antibody
Regulatory Class: II
Product Code: KTL
Dated: March 12, 1999
Received: March 18, 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/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: ~~Not Known~~ K990916

Device Name: Indirect Fluorescence Assay (IFA) for Anti-native DNA (nDNA) IgG Antibody

Indications For Use: The Stellar Bio Systems' Indirect Fluorescence Assay (IFA) for Anti-native DNA (nDNA) IgG Antibody is intended for the qualitative and semi-quantitative detection of IgG (Immunoglobulin G) antibody to nDNA in human serum. Detection of nDNA IgG antibody in humans can be used as an aid in the diagnosis of systemic lupus erythematosus (SLE).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990916

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)