SEP 3 1999

K991274

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 29, 1999
Name:	Columbia Bioscience, Inc.
Address:	8775 M Centre Park Ddrive, #559 Columbia, MD 21045
Contact Person:	Norman Jenkins
PhoneNumber:	410-995-1278
Fax Number	410-995-0508

Device Information:

Trade Name:	Mumps IgG ELISA Kit
Common Name:	Mumps IgG EIA Test
Classification Name:	Mumps Serological Reagent

Equivalent Device: Wampole Mumps IgG ELISA Kit

Device Description: The Mumps IgG ELISA Kit is an Enzyme-Linked ImmunoSorbent Assay (ELISA) for the detection of IgG antibodies to Mumps antigen in human serum.

Intended Use: For the qualitative and semi-quantitative determination of IgG antibodies to Mumps virus in human serum of adults over eighteen years of age by indirect enzyme immunoassay as an aid in the diagnosis of Mumps infection. The evaluation of paired sera, to determine a significant increase in Mumps IgG antibody titer can also aid in the diagnosis of acute infection by seroconversion determination through testing acute and convalescent sera. The test can be performed either manually or in conjunction with the MAGO® Plus Automated EIA processor. Performance characteristics have not been established on children.

Principle of Procedure:
Purified Mumps antigen is bound to microwells. Diluted patient sera, Cut-Off Calibrator and controls are placed in the microwells and incubated. Anti-Mumps IgG antibodies, if present, will bind to the antigen forming antigen-antibody complexes. Residual sample is eliminated by aspirating and washing. Conjugate (horseradish peroxidase-labeled anti-human IgG) is added and will bind to these complexes. Unbound conjugate is removed by aspiration and washing. Substrate is then added and incubated. In the presence of bound enzyme the substrate is converted to an end product. The absorbance of this end product can be read spectrophotometrically at 450 nm (reference 600-630 nm) and is directly proportional to the concentration of IgG antibodies to Mumps present in the sample.

Performance Characteristics

A. Comparison with Another ELISA Test

Fresh sera from one hundred seventy-three patients were tested at a clinical commercial laboratory, located in the Mid-Atlantic area, using the *Is*-Mumps IgG Test Kit and a commercially available kit for Mumps IgG antibodies. The data in Table 1 show the relative sensitivity, specificity and overall agreement of the *Is*-Mumps IgG Test Kit versus this commercial Mumps IgG ELISA.

TABLE 1

***Is*-Mumps IgG Test Kit**

Other ELISA	POSITIVE	*EQUIVOCAL	NEGATIVE
POSITIVE	160	0	0
*EQUIVOCAL	0	0	0
NEGATIVE	3**	3***	10

		95% CI
Relative Sensitivity =	160/160 = 100%	97.7% - 100%
Relative Specificity =	10/13 = 76.9%	46.2% - 95.0%
Overall Agreement =	170/173 = 98.3%	95.0% - 99.6%

* Equivocal results were excluded from calculations.
** 3/3 sera were positive by IFA.
*** 3/3 sera were positive by IFA.

NOTE : Please be advised that 'relative' refers to the comparison of the 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's accuracy to predict disease.

B. Reproducibility

To determine the reproducibility of the *Ix*-Mumps IgG Test Kit, four positive and two negative sera were assayed ten times each in three different runs at three different sites. The 3 sites included: the manufacturer, a research and development laboratory, and a clinical commercial laboratory. The intra- and interassay reproducibility obtained at each site is shown in Tables 2, 3 and 4.

TABLE 2 : **Site #1 - Intra-Assay and Interassay Reproducibility**

SERUM	INTRA-ASSAY RUN 1 MEAN INDEX	CV%	INTRA-ASSAY RUN 2 MEAN INDEX	CV%	INTRA-ASSAY RUN 3 MEAN INDEX	CV%	INTERASSAY MEAN INDEX	CV%
A (POS)	1.11	4.26	1.17	8.82	1.24	8.90	1.17	8.70
B (POS)	1.26	5.19	1.34	6.04	1.38	4.82	1.33	6.36
C (POS)	1.95	9.02	2.02	5.33	2.17	4.22	2.05	7.55
D (POS)	1.74	7.27	1.64	6.67	1.73	7.68	1.70	7.48
E (NEG)	0.15	40.25	0.18	23.53	0.23	21.39	0.18	32.18
F (NEG)	0.14	39.81	0.13	39.09	0.16	39.88	0.14	39.03

TABLE 3 : **Site #2- Intra-Assay and Interassay Reproducibility**

SERUM	INTRA-ASSAY RUN 1 MEAN INDEX	CV%	INTRA-ASSAY RUN 2 MEAN INDEX	CV%	INTRA-ASSAY RUN 3 MEAN INDEX	CV%	INTERASSAY MEAN INDEX	CV%
A (POS)	1.188	6.30	1.248	6.53	1.371	9.35	1.269	9.63
B (POS)	1.384	10.51	1.338	6.30	1.515	6.57	1.412	9.43
C (POS)	2.110	6.94	1.976	6.74	2.247	8.75	2.111	9.09
D (POS)	1.673	4.86	1.738	7.98	1.949	5.05	1.787	8.92
E (NEG)	0.227	9.44	0.247	15.95	0.314	11.60	0.263	18.86
F (NEG)	0.175	8.14	0.198	4.37	0.228	8.18	0.200	13.02

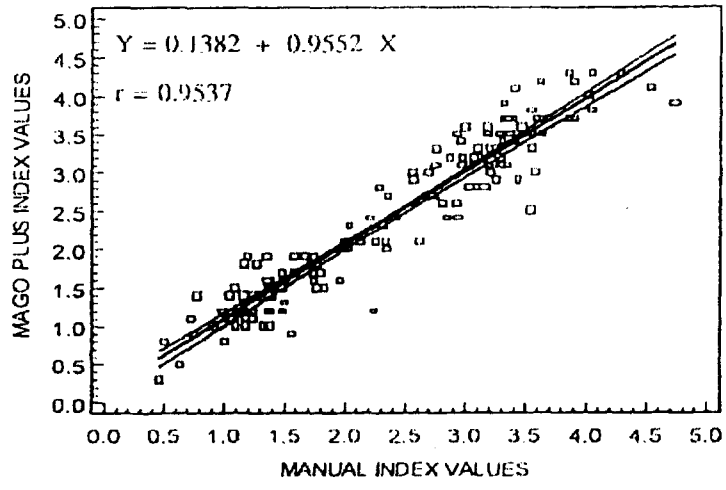
TABLE 4 : **Site #3 - Intra-assay and Interassay Reproducibility**

SERUM	INTRA-ASSAY RUN 1 MEAN INDEX	CV%	INTRA-ASSAY RUN 2 MEAN INDEX	CV%	INTRA-ASSAY RUN 3 MEAN INDEX	CV%	INTERASSAY MEAN INDEX	CV%
A (POS)	1.21	10.20	1.24	7.00	1.18	6.15	1.21	8.04
B (POS)	1.31	4.49	1.31	2.57	1.31	5.12	1.31	4.06
C (POS)	2.10	7.04	2.08	5.84	2.09	6.51	2.09	6.28
D (POS)	1.83	5.75	1.71	8.72	1.67	4.69	1.74	7.54
E (NEG)	0.28	34.40	0.24	15.53	0.16	24.35	0.23	35.19
F (NEG)	0.20	15.41	0.21	8.87	0.16	15.88	0.19	17.49

C. Correlation of Manual and MAGO Plus Results

The *Ix*-Mumps IgG Test Kit has been developed for automated as well as manual use. To demonstrate the equivalence of the manual and MAGO Plus procedures, the results of 153 serum samples, tested by both methods, were plotted. A scattergram and regression line of the results obtained with 95% confidence intervals is shown in Figure 1. The data indicate good correlation with a Pearson Correlation Coefficient of 0.954.

FIGURE I : Manual and MAGO Plus Result Correlation



D. MAGO Plus Reproducibility

The reproducibility of the assay when performed on the MAGO Plus Automated EIA Processor was determined by assaying six sera ten times each in three different runs. Table 5 shows the intra-and interassay reproducibility obtained using the MAGO Plus.

TABLE 5 : Site #2- Intra-Assay and Interassay Reproducibility - MAGO Plus

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.2	9.26	1.3	10.04	1.2	9.91	1.2	10.03
B (POS)	1.4	11.60	1.5	6.92	1.5	13.06	1.5	11.50
C (POS)	2.2	10.96	2.3	8.93	2.3	8.72	2.2	9.62
D (POS)	1.9	10.27	1.9	8.06	1.8	8.42	1.9	8.84
E (NEG)	0.2	28.41	0.2	0.00	0.2	23.57	0.2	21.19
F (NEG)	0.1	0.00	0.1	28.75	0.1	28.75	0.1	23.79

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 3 1999

DIAMEDIX Corporation
c/o Mr. William Boteler
ImmunoProbe, Inc.
1306F Bailes Lane
Frederick, Maryland 21701

Re: K991274
Trade Name: Mumps IgG ELISA Test System
Regulatory Class: I
Product Code: LJY
Dated: June 25, 1999
Received: June 28, 1999

Dear Mr. Boteler:

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: Not Known

Device Name: Mumps IgG ELISA

Indications For Use: For the qualitative and semi-quantitative determination of IgG antibodies to Mumps virus in human serum of adults over eighteen years of age by indirect enzyme immunoassay as an aid in the diagnosis of Mumps infection. The evaluation of paired sera, to determine a significant increase in Mumps IgG antibody titer, can also aid in the diagnosis of acute infection by seroconversion determination through testing acute and convalescent sera. The test can be performed either manually or in conjunction with the MAGO® Plus Automated EIA processor. Performance characteristics have not been established on children.

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)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991274