NOV 25 1998

K981651



# 510(k) SUMMARY

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: K981651

A. Safety and effectiveness information required per [§807.92(a)(1)]:

- **SUBMITTER'S NAME:** BioStar, Inc.
- **ADDRESS:** 6655 Lookout Rd. Boulder, CO 80301
- **TELEPHONE:** (303) 530-3888 ext. 603
- **FAX:** (303) 530-6601
- **CONTACT PERSON:** Roger C. Briden
- **DATE 510(k) SUMMARY PREPARED:** September 18, 1998

B. Safety and effectiveness information required per [§807.92(a)(2)]:

- **TRADE OR PROPRIETARY NAME:** AB FLU OIA®
- **COMMON NAME:** Influenza Assay
- **CLASSIFICATION NAME:** Direct Antigen Detection Assay, Influenza Virus A, B

C. Identification of legally marketed device to which we are claiming equivalence [§807.92(a)(3)]:

- TRADE OR PROPRIETARY NAME: Directigen® Flu A
- REGULATORY CLASS: Class I
- PRODUCT CODE: 83GNT
- MANUFACTURER: Becton Dickinson® and Co.
- 510(k) NUMBER: K902609

Note: Performance of the AB FLU OIA product was established versus cell culture.

D. Description of device [§807.92(a)(4)]:

Principle of the Test:

The AB FLU OIA test involves the extraction and detection of a protein antigen unique to influenza A or B (nucleoprotein). The Optical ImmunoAssay technology enables the direct visual detection of a physical change in the optical thickness of molecular thin films. This change is a result of antigen-antibody binding on an optical surface (silicon wafer). When extracted specimen is placed directly on the optical surface, the immobilized specific antibodies capture the antigen. After washing, the substrate is added, increasing the thickness (Mass Enhancement) of the molecular thin film. This change in thickness alters the reflected light path and is visually perceived as a color change. Slight changes in optical thickness produce a distinct visible color change. A positive result appears as a purple spot on the predominant gold background. When antigen is not present in the specimen, no binding takes place. Therefore, the optical thickness remains unchanged and the surface retains the original gold indicating a negative result

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Device Components:

The AB FLU OIA test kit contains the following:

Sample Diluent
Reagent 1: Specimen Extraction Reagent
Reagent 2: Conjugate
Wash
Substrate
Positive Control
Negative Control
Extraction Tubes
Test Devices
Transfer Pipettes
Sterile Rayon Swabs

E. Intended use of device [§807.92(a)(5)]:

The BioStar® AB FLU OIA® assay is an Optical ImmunoAssay (OIA) test for the qualitative, rapid detection of influenza A and B viral antigen (nucleoprotein) from nasal aspirate, nasopharyngeal swab, throat swab, or sputum specimens. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of influenza A and B viral infections. The AB FLU OIA test is not intended to detect influenza C. Negative test results should be confirmed by cell culture.

F. Technological characteristics [§807.92(a)(6)]:

| Technological Characteristic | Predicate Device (Directigen Flu A) | Our Device (AB FLU OIA) |
|---|---|---|
| Intended Use | The Directigen Flu A Test is an in vitro enzyme immunoassay (EIA) membrane test for the direct rapid and qualitative detection of influenza A viral antigen from suitable specimens of symptomatic patients. Nasopharyngeal wash and aspirate specimens have been shown to be superior to nasopharyngeal and throat swab specimens and are the specimens of choice with the Directigen Flu A Test. | The BioStar® AB FLU OIA® assay is an Optical ImmunoAssay (OIA) test for the qualitative, rapid detection of influenza A and B viral antigen (nucleoprotein) from nasal aspirate, nasopharyngeal swab, throat swab, or sputum specimens. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of influenza A and B viral infections. The AB FLU OIA test is not intended to detect influenza C. Negative test results should be confirmed by cell culture. |
| Detection | Detects Influenza A nucleoproteins. | Detects Influenza A and B nucleoproteins. |
| Technology | Enzyme Immunoassay (EIA) Membrane | Optical Immunoassay (OIA) |
| Specimens Evaluated | Nasopharyngeal wash, nasopharyngeal aspirate, nasopharyngeal swab, throat swab. | Sputum, nasal aspirate, nasopharyngeal swab, throat swab. |

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G. Summary of nonclinical testing [§807.92(b)(1)]:

Analytical Sensitivity:

The analytical sensitivity was evaluated using 11 influenza strains: 7 influenza A and 4 influenza B strains. Duplicate dilutions of each viral strain were prepared in Phosphate Buffered Saline (PBS) and tested according to the AB FLU OIA Test Procedure. Viral detection limit tested in the AB FLU OIA test ($TCID_{50}$/test) was determined by inoculating dilutions in cell culture to estimate $TCID_{50}$.

| Viral Strain | Viral Type | Detection Limit |
|---|---|---|
| Hong Kong/68 H3N2 | A | $2.6 \times 10^3$ |
| Shangdong/9/93 H3N2 | A | $1.2 \times 10^4$ |
| Texas/36/91 H1N1 | A | $7.1 \times 10^3$ |
| Wuhan/359/95 H3N2 | A | $1.3 \times 10^3$ |
| Bayern/7/95 H1N1 | A | $2.3 \times 10^3$ |
| Singapore/1/57 H2N2 | A | $5.0 \times 10^2$ |
| Hong Kong/156/97 H5N1 | A | $5.3 \times 10^3$ |
| Panama/45/90 | B | $1.3 \times 10^4$ |
| Beijing/184/93 | B | $9.4 \times 10^2$ |
| Guangdong/5/94 | B | $6.0 \times 10^3$ |
| Victoria/2/87 | B | $1.2 \times 10^3$ |

Reactivity:

To demonstrate reactivity across a broad spectrum of influenza strains, the AB FLU OIA test was performed on a number of additional human and non-human strains.

A/NWS/33 (H1N1)
A/Swine/1976/31
A/New Jersey/8/76 (HswN1)
A/Japan/170/62 (H2N2)
A/Puerto Rico/8/34 (H1N1)
A2/Taiwan/1/64 (H2N2)
A/Port Chalmers/1/73 (H3N2)
A/Victoria/3/75 (H3N2)
A/Duck/Ukraine/1/63 (H3N8)
A/Duck/Czechoslovakia/56 (H4N6)
A/Chicken/Hong Kong/1203/97 (H5N1)
A/Duck/Pennsylvania/10218/84 (H5N2)
A/Shearwater/Australia/1/72 (H6N5)
A/Equine 1/Prague/1/56 (H7N7)
A/Turkey/Oregon/1/74 (H7N3)
A/Turkey/Ontario/6118/68 (H8N4)
A/Chick/Germany/N/48 (H10N7)

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A/Duck/England/56 (H11N6)
A/Duck/Alberta/60/76 (H12N6)
A/Gull/Maryland/704/77 (H13N6)

Analytical Specificity (Cross Reactivity):

To determine the analytical specificity of the AB FLU OIA test, the organisms and viruses listed in the bacterial and viral panels presented in the product package insert were grown in culture and tested at appropriate concentrations. A sample of each organism and virus was tested in duplicate. Cell density or viral titer was confirmed by plating an aliquot of suspension, growing the organism or virus, and counting the number of colonies or plaques formed. None of the organisms or viruses listed in the panels gave a positive result in the AB FLU OIA test.

Interfering Substances:

A variety of substances were obtained which might interfere with the effectiveness of the AB FLU OIA test if encountered during the collection of specimens. Each substance was prepared in a manner and concentration so as to exceed the likely conditions and amounts found *in situ*. Each substance was tested in three independent analyses: In the absence of influenza virus, in the presence of only Influenza A (A/Hong Kong), and in the presence of only Influenza B (B/Panama). In addition, a saline control was tested in the same manner. All assays were run per the testing procedure described in the package insert. None of the specimens tested gave a positive signal when virus was not present in the sample. No decrease in signal strength was noted for either influenza A or B in the presence of either blood, or several commercially available mouth washes, throat sprays, cough lozenges, nasal sprays, or cough/cold elixirs.

H. Summary of clinical testing [§807.92(b)(2)]:

The performance of the AB FLU OIA assay was compared to conventional methods for influenza culture in an evaluation of clinical specimens. In a three-site study to compare the AB FLU OIA assay with culture, any combination of dual throat and dual nasopharyngeal swabs, nasal aspirate and sputum specimens were collected from 184 individuals exhibiting influenza-like symptoms. Patients of any age or sex were included in this study.

The influenza prevalence rate by site, as determined by confirmed culture from any specimen type, was 56.1% at site 1(Rocky Mountain region), 56.9% at site 2 (Midwest region), and 41.0% at site 3 (Southwestern region). The table below summarizes the sensitivity and specificity of the AB FLU OIA test relative to 14-day culture for the four specimen types collected during the clinical study. The four specimen types identified in the table are nasal aspirate (NA), nasopharyngeal swab (NPS), throat swab (TS), and sputum (SP). For additional information regarding data collection and analysis, see the product package insert.

| D. Specimen Type | E. Relative Sensitivity | F. Relative Specificity |
|---|---|---|
| NA | 88.4 % | 69.4% |
| NPS | 83.3% | 76.2% |
| TS | 62.1% | 79.5% |
| SP | 81.1% | 51.5% |

I. Conclusions from nonclinical / clinical testing [§807.92(b)(3)]:

In evaluating the cross reactivity of the AB FLU OIA test with organisms and viruses listed in the bacterial and viral panels presented in the product package insert, none of the organisms or viruses gave a positive result in the AB FLU OIA test. At levels exceeding those likely be encountered in situ during sample collection, neither blood, nor several commercially available mouthwashes, throat sprays, cough lozenges, nasal sprays, or cough/cold elixirs interfered with the test. These results combined with the analytical sensitivity, along with the relative sensitivity and specificity calculated from the clinical study data demonstrate that the AB FLU OIA test is safe and effective.

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I. Additional information [§807.92(d)]:

No additional information has been requested by FDA at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 25 1998

Roger Briden, Ph.D.
Director, RA/QA
BioStar, Inc.
6655 Lookout Road
Boulder, CO 80301

Re: K981651
Trade Name: BioStar® AB FLU OIA
Regulatory Class: I
Product Code: GNX
Dated: September 18, 1998
Received: September 22, 1998

Dear Dr. Briden:

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): K981651

Device Name: BioStar®, Inc. AB FLU OIA

Indications For Use: The BioStar® FLU OIA assay is an Optical ImmunoAssay (OIA) test for the qualitative, rapid detection of influenza A and B viral antigen (nucleoprotein) from nasal aspirate, nasopharyngeal swabs, throat swabs, or sputum specimens. This test is intended for *in vitro* use to aid in influenza A and B viral infections. The FLU OIA is not intended to detect influenza C. Negative test results should be confirmed by culture [isolation].

(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 K981651

Prescription Use ✘ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)