MAR 2 7 2003

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: ___K023556_____

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

- **SUBMITTER'S NAME:** Thermo BioStar, Inc.
- **ADDRESS:** 331 South 104th Street
- **TELEPHONE:** (303) 530-3888 ext. 612
- **FAX:** (303) 581-6405
- **CONTACT PERSON:** John G. Adams
- **DATE 510(k) SUMMARY PREPARED:** October, 2002; revised March, 2003

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

- **TRADE OR PROPRIETARY NAME:** FLU OIA® A/B
- **COMMON NAME:** Influenza Rapid Assay
- **CLASSIFICATION NAME:** Antigen, CF (including CF Controls), Influenza Virus A, B, C

C. Identification of legally marketed device to which we are comparing performance.

Device Technology:

Trade or Proprietary Name:	AB FLU OIA test kit
Regulatory Class:	I
Manufacturer:	Thermo BioStar
510(k) Number:	K981651

Historical Reference Method:

Viral Culture

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

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

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

Principle of the Test:

The FLU OIA A/B 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 an 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 color indicating a negative result.

DEVICE COMPARISON:

Device Technology:

The FLU OIA A/B assay addressed in this submission is identical to the FLU OIA assay previously cleared in that:

- Both assays are rapid diagnostic tests that utilize Optical ImmunoAssay technology
- Both assays are used to detect and identify antigen proteins specific to influenza A and influenza B infections.
- Both assays can provide results in less than 20 minutes.
- Both assays are qualitative.
- Neither assay is intended to detect influenza C .

The FLU OIA A/B assay differs from the currently marketed FLU OIA assay in that:

- The original FLU OIA assay (K981651) does not differentiate A from B influenza antigens. FLU OIA A/B allows for the independent identification of viral type A and viral type B antigens from the same specimen.

SUMMARY OF PERFORMANCE DATA:

ANALYTICAL and CLINICAL Comparison

Performance characteristics for the original AB FLU OIA assay were initially established in a multi-center study with geographically diverse clinical sites. The analytical sensitivity and specificity of the FLU OIA A/B test is equivalent to that of the FLU OIA test, as measured by comparability studies carried out using inactivated virus standards, live virus strains, and a panel of retrospective frozen clinical specimens.

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

Reproducibility

Inter-Laboratory

Representatives of three POL or clinic sites, and one internal Thermo BioStar site conducted reproducibility testing. Individual panels were prepared , each containing nine blinded specimens and two controls. Each panel was performed on three different occasions, by personnel from the four different laboratories. The samples consisted of throat swabs spiked with negative, high negative, low positive, moderate positive, and high positive specimens for each virus type. These samples were spiked onto swabs for analysis.

Overall reproducibility for the sample panel was 96.6% across all sites (255/264).

Intra-Laboratory

Reproducibility of the assay was evaluated by testing specimens at or near the cut-off in multiple replications (n=20). The cut-off was defined as the level of virus at which it would be expected that the assay would be positive 50% of the time and negative 50% of the time.

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Clinical Sample Comparison

A retrospective analysis was conducted of previously collected clinical data comparing the FLU OIA test to commercially available cell culture, with confirmation and typing by fluorescent antibody staining. A total of 184 patients were enrolled into the multi-center study. Data available for analysis included 151 specimens that were positive by culture. Of the 151, 129 were confirmed as Influenza A and 22 were confirmed as Influenza B. Sensitivity to Influenza A is calculated as 82.9% (95%C.I. = 75.3-89.0), and sensitivity to Influenza B is calculated as 63.6% (95% C.I.= 40.7-82.8%)

The performance of the FLU OIA A/B assay was also compared to the original FLU OIA assay on 112 retrospective frozen clinical specimens. For positive specimens (4) agreement was 100% (95% CI = 39.8 – 100). Overall agreement was 100% (95% CI = 96.8 – 100)

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

Analytical testing was performed on both microbial and viral panels to assess specificity and cross reactivity.

Whole blood and several types of over the counter (OTC) products were evaluated to assess the potential for interference.

The results of the above described internal and external studies demonstrated that the FLU OIA A/B is safe and effective .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 27 2003

Mr. John G. Adams
Regulatory Affairs
Thermo BioStar
331 South 104th Street
Louisville, CO 80027

Re: k023556
Trade/Device Name: FLU OIA ® A/B Test Kit
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: January 25, 2003
Received: January 28, 2003

Dear Mr. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

12.0 INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K023556

Device Name: FLU OIA® A/B

Indications For Use:

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

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023556

Over-The-Counter Use

(Optional Format 1-2-96)