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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: K023779

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

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

- **TRADE OR PROPRIETARY NAME:** RSV OIA®
- **COMMON NAME:** Respiratory Syncytial Virus assay
- **CLASSIFICATION NAME:** Antigen, , CF (including CF Controls), Respiratory Syncytial Virus

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

Device Technology:

Trade or Proprietary Name:	RSV OIA test kit
Regulatory Class:	I
Manufacturer:	Thermo BioStar
510(k) Number:	K021172

Historical Reference Method:

Viral Culture

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

The Thermo BioStar® RSV OIA assay is an Optical ImmunoAssay test for the rapid and qualitative detection of respiratory syncytial virus (RSV) antigens (nucleoproteins and fusion proteins) from nasal wash and nasopharyngeal swab specimens. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in symptomatic neonatal and pediatric patients under the age of five. It is recommended that all negative test results be confirmed by cell culture.

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

Principle of the Test:

The RSV OIA test involves the qualitative extraction and detection of protein antigens unique to RSV (nucleoprotein and fusion protein). 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 RSV OIA assay addressed in this submission is identical to the RSV 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 RSV infections.
- Both assays can provide results in less than 20 minutes.
- Both assays are qualitative.

The RSV OIA assay differs from the currently marketed RSV OIA assay in that:

- The original RSV OIA assay (K021172) specimen types are limited to nasal wash specimens, and do not include nasopharyngeal swab specimens.

Comparison to historical standard method:

The RSV OIA assay is similar to culture methods in that:

- Both assays are used to detect and identify respiratory syncytial virus.
- Both assays can detect the RSV virus from nasal wash and nasopharyngeal swab specimens.
- Both assays are qualitative

The RSV OIA assay differs with traditional culture methods in that:

- RSV OIA assay detects an antigen unique to the respiratory syncytial virus while the traditional culture methods detect the whole living organism.
- RSV OIA assay can provide results in less than 20 minutes, in contrast to culture methods that can take in excess of 48 hours.

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SUMMARY OF PERFORMANCE DATA:

CLINICAL STUDIES

Performance characteristics for the RSV OIA assay were initially established in a multicenter study with geographically diverse clinical sites.

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

Reproducibility

Reproducibility testing was conducted at four hospital laboratories and two physician office laboratories (POL). Nine blinded samples were tested at each site at three separate times. The samples consisted of negative, low and moderate levels of RSV antigen, and the Kit positive and negative controls. These samples were prepared in buffered protein solution, and were spiked onto swabs for analysis. The reproducibility study included both the swab extraction and OIA testing of the antigen associated with RSV.

There were no significant differences in performance among the sites. Overall reproducibility for the sample panel was 95% across all sites (151/159).

Clinical Sensitivity and Specificity

A study was conducted comparing the RSV OIA test to commercially available cell culture, with confirmation and typing by fluorescent antibody staining. Secondary confirmation testing of specimens positive to OIA and negative to culture was done by specific nucleic acid detection by PCR . A total of 491 patients were enrolled into the multicenter study. A total of 414 nasalpharyngeal specimens were included in the data analysis, with 77 specimens excluded.

The RSV OIA assay was evaluated versus cell culture with confirmation and typing by fluorescent antibody staining. Sensitivity and specificity for symptomatic patients was 86.8% and 83.2% respectively for nasal wash specimens. Sensitivity and specificity for symptomatic patients and nasopharyngeal swabs was 66.7% and 96.4% respectively.

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 RSV OIA test is as safe and effective as the comparative devices.

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 4 2003

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

Re: k023779
Trade/Device Name: RSV OIA®
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory Syncytial Virus Serological Reagents
Regulatory Class: Class I
Product Code: GQG
Dated: November 8, 2002
Received: November 12, 2002

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): K023779

Device Name: RSV OIA®

Indications For Use:

The Thermo BioStar® RSV OIA assay is an Optical ImmunoAssay test for the rapid and qualitative detection of respiratory syncytial virus (RSV) antigens (nucleoproteins and fusion proteins) from nasal wash and nasopharyngeal swab specimens. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in symptomatic neonatal and pediatric patients under the age of five. It is recommended that all negative test results 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)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Freddie M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023779