APR 17 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: _____K023947___

A. Submitter's information required per [§807.92(a)(1)]:

- **SUBMITTER'S NAME:** Thermo BioStar, Inc.
- **ADDRESS:** 331 South 104th Street, Louisville CO 800271
- **TELEPHONE:** (303) 530-3888 ext. 612
- **FAX:** (303) 581-6405
- **CONTACT PERSON:** John G. Adams

- **DATE 510(k) SUMMARY PREPARED:** April, 2003

B. Device information required per [§807.92(a)(2)]:

- **TRADE OR PROPRIETARY NAME:** GC OIA®
- **COMMON NAME:** *Neisseria gonorrhoeae* antigen assay
- **CLASSIFICATION NAME:** Antigen, Enzyme Linked Immunoabsorbent Assay, *Neisseria gonorrhoeae*

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

Historical Reference Method
- *Neisseria gonorrhoeae* culture

Device Technology:

Trade or Proprietary Name:	Chlamydia OIA Assay
Regulatory Class:	I
Manufacturer:	Thermo BioStar
510(k) Number:	K951010

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

The Thermo BioStar® GC OIA assay is an Optical ImmunoAssay test for the rapid qualitative detection of gonococcal antigen (L7/L12 ribosomal protein) in female endocervical swab and male urine specimens. Urine specimens must be prepared using an accessory Urine Filtration Device (UFD) for concentration and extraction. This test is intended for *in vitro* diagnostic use as an aid in identifying the presence of *Neisseria gonorrhoeae* antigen. The assay is intended for use with symptomatic females and males, in populations at risk for sexually transmitted diseases.

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

Principle of the Test:

The GC OIA test involves the qualitative extraction and detection of an antigen unique to *N. gonorrhoeae*. 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. An antibody-enzyme conjugate is then added for form an immune complex "sandwich" of immobilized antibody-sample-antibody HRP on the surface. 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.

F. Device Comparison [§807.92(a)(6)]:

Comparison to Historical reference method

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

- Both assays are used to detect and identify *N. gonorrhoeae ;*
- Both assays detect *N. gonorrhoeae* in endocervical swabs and male urine specimens.

The GC OIA assay differs from traditional culture methods in that:

- GC OIA assay detects an antigen unique to the *N. gonorrhoeae* organism, while the traditional culture methods detect the whole living organism;
- The GC OIA assay can provide results in less than 30 minutes, in contrast to culture methods that can take up to 72 hours.

Comparison to existing device technology

The GC OIA assay is similar to the Chlamydia OIA assay in that:

- Both assays have the same Optical ImmunoAssay (OIA) technology;
- Both assays detect antigen in endocervical swab specimens;
- The intended use for both assays is to evaluate symptomatic patients for a sexually transmitted disease infection;
- Both assays are qualitative;
- Both assays utilize liquid reagents

The GC OIA assay differs with the Chlamydia assay in that:

- GC OIA is testing for the presence of a different STD, *Neisseria gonorrhoeae*;
- GC OIA detects antigens in symptomatic male urine specimens, in addition to endocervical swabs

SUMMARY OF PERFORMANCE DATA:

CLINICAL STUDIES

Performance characteristics for the GC OIA assay were initially established in a multicenter study at four geographically diverse clinical sites.

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

Reproducibility

Urine: Reproducibility testing was conducted at four clinical sites and two point of care settings including physician offices. Urine testing was performed with 2 mL samples on three days with nine blinded specimens each day. This testing resulted in an overall reproducibility of 98.1% (95%CI = 93.8-99.3).

Swab: Reproducibility testing was conducted at three physician office laboratories. Swab testing was performed on three days with nine blinded samples each day. The negative swabs contained no GC cells. Overall reproducibility of the testing using the swab panels was 88.9% at the three sites. (95% CI = 93.8-99.3)

Clinical Sensitivity and Specificity

A study comparing the GC OIA test to commercial culture media, with secondary confirmation testing by LCR (Ligase Chain Reaction). A total of 904 valid results were obtained from symptomatic patient specimens collected at four clinical trial locations. Sensitivity and specificity for symptomatic male urines was 93.2 % and 97.5 % respectively. Sensitivity and specificity for symptomatic female endocervical swabs was 70.7% and 99.4% respectively. Overall PPV and NPV for males were 94.0 % and 97.2 % respectively; and for females were 90.6% and 97.5% respectively.

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

The results of the above described internal and external studies demonstrate that the GC OIA test is as safe and effective as the comparative device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 17 2003

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

Re: k023947
Trade/Device Name: GC OIA® Test Kit
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. Direct Serological Test Reagents
Regulatory Class: Class II
Product Code: LIR
Dated: February 18, 2003
Received: February 19, 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): K 023947

Device Name: GC OIA®

Indications For Use:

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(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)

Peter Cummings for Freddie Poole April 14, 2003

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023947