8.0 510(k) SUMMARY (page 1 of 5)

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: 991828

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: April 20, 1999

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

- TRADE OR PROPRIETARY NAME: STREP B OIA®
- COMMON NAME: Group B Strep
- CLASSIFICATION NAME: Antigens, All Groups, Streptococcus spp

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

- TRADE OR PROPRIETARY NAME: STREP B OIA®
- REGULATORY CLASS: Class I
- PRODUCT CODE: 83GTY
- MANUFACTURER: BioStar, Inc.
- 510(k) NUMBER: K936112

Note: Performance of the STREP B OIA product was established versus Lim broth as the reference standard.

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

Principle of the Test:

The STREP B OIA test involves the extraction of a carbohydrate antigen unique to group B Streptococci from the cervical or vaginal swab specimen and the subsequent use of Optical ImmunoAssay technology for the qualitative detection of this specific antigen. The Optical ImmunoAssay technology allows the direct visual detection of the physical change in optical thickness of molecular thin films resulting from the binding reactions between antibodies and antigens. The signal is generated by the change in the reflection of light through the molecular thin films formed on an optical substrate.

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White light reflected through the molecular thin film results in a predominant visual background gold color. This color will not change unless the thickness of the optical molecular thin film is changed (Figure 1). When a liquid sample containing antigen from group B Streptococci is placed on the test surface, binding occurs between the antigen and immobilized antibody, causing an increased thickness in the molecular thin film. Once this reaction takes place, the optical path through the film is changed, causing a corresponding change in the gold color to purple/blue, thereby indicating a positive result. The change in optical thickness is due to the binding of specific antigen. If the antigen is not present in the sample, no binding takes place. The original molecular thickness remains unchanged and the test surface retains its original gold color, indicating a negative result. The clear endpoint and unequivocal results observed with the optical detection system lead to a very sensitive easily interpreted assay system.

Device Components:

The STREP B OIA test kit contains the following:

Extraction Tubes
Reagent 1A, extraction reagent
Reagent 1B, extraction reagent
Reagent 2, neutralization reagent
Reagent 3, Conjugate
Reagent 4, wash solution
Reagent 5, Substrate
Test Devices
Positive Control
Transfer Pipettes
Swabs

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

The BioStar® STREP B OIA® assay is an Optical ImmunoAssay (OIA) test for the rapid detection of group B streptococcal antigen directly from cervical and vaginal swabs from intrapartum maternity patients. The STREP B OIA assay is intended for use as an adjunct to culture, clinical observation and other information available to the physician.

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

There are no changes. This is the same device used to establish performance versus TSA culture in K936112 and versus Lim broth in this submission.

Technological Characteristic	Predicate Device (Strep B OIA®)	Our Device (STREP B OIA®)
Intended Use	The BioStar® Strep B OIA® assay is an Optical ImmunoAssay (OIA) test for the rapid detection of Group B Streptococcal antigen directly from cervical and vaginal swabs from preterm and intrapartum maternity patients. The Strep B OIA is intended for use as an adjunct to culture, clinical observation and information available to the physician.	The BioStar® STREP B OIA® assay is an Optical ImmunoAssay (OIA) test for the rapid detection of group B streptococcal antigen directly from cervical and vaginal swabs from intrapartum maternity patients. The STREP B OIA assay is intended for use as an adjunct to culture, clinical observation and other information available to the physician.
Detection	Detects group B streptococcal antigen	Detects group B streptococcal antigen
Technology	OIA®(Optical Immunoassay)	OIA®(Optical Immunoassay)
Specimens Evaluated	Cervical / Vaginal swab	Cervical / Vaginal swab

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

Only the clinical data has changed therefore the information provided here is what exists in the package insert for the cleared product.

Analytical Sensitivity:

LIMITS OF DETECTION

GBS cells of Subtypes Ia, Ib, Ic, II, III were grown on TSA / 5% sheep blood agar plates, harvested and diluted in saline. The diluted suspensions were enumerated by culture on TSA / 5% sheep blood agar plates. The following table presents the lowest concentration of each subtype giving a positive result in the assay.

Subtype	Strain	OIA Sensitivity (Cells / Assay)
Ia	CDC SS-880	$1.6X10^4$
Ib	CDC SS-884	$1.4X10^4$
Ic	CDC SS-1070	$1.6X10^4$
II	CDC SS-888	$8.7X10^3$
III	CDC SS-893	$7.7X10^3$

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Analytical Specificity (Cross Reactivity):

ANALYTICAL SPECIFICITY (CROSS REACTIVITY)

To determine the analytical specificity of the STREP B OIA test, the following organisms were grown in culture and tested at a concentration of at least 10^7 organisms/test. Cell density was confirmed by plating an aliquot of the suspension, growing the organism and counting the number of colonies formed. None of the organisms listed below gave a positive result in the STREP B OIA test.

Staphylococcus aureus
(Protein A Producer)
Staphylococcus aureus
Enterococcus faecalis
Staphylococcus epidermidis
Moraxella catarrhalis
Klebsiella pneumoniae
Pseudomonas aeruginosa
Escherichia coli
Streptococcus pneumoniae
Lactobacillus fermentum
Peptostreptococcus anaerobius
Proteus mirabilis
Salmonella cholerarsuis
subspecies *cholerarsuis*
serotype: *minnesota*
Salmonella cholerarsuis
subspecies *cholerarsuis*
serotype: *minnesota (R595)*
Salmonella cholerarsuis
subspecies *cholerarsuis*
serotype: *typhimurium*
Gardnerella vaginalis
Streptococcus Group A
Streptococcus Group F
Eubacterium lentum
Streptococcus Group G
Haemophilus influenzae
Streptococcus equi, ssp. equi .
Acinetobacter calcoaceticus
Candida glabrata
Neisseria gonorrhoeae
Moraxella lacunata
Peptostreptococcus productus
Candida albicans

In addition, these organisms were cultured and tested and found to not interfere with the test.

HSV-1
HSV-2
Trichomonas vaginalis

Interfering Substances:

The following substances have been tested and do not interfere with the STREP B OIA test methodology: urine, amniotic fluid, vaginal mucous and sheep blood agar.

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

The performance of the STREP B OIA assay was compared to that of routine microbiological Trypticase Soy Agar with 5% Sheep Blood (TSA) culture media and selective broth culture using Lim broth in a prospective evaluation of clinical specimens taken from women in labor. In a multi-site study comparing the STREP B OIA test with Selective broth culture, cervical and vaginal specimens were collected using standard techniques from 947 women using a dual swab (Duo-Transtube® swabs- Medical Wire and Equipment Co., Sparta, NJ). One swab was plated onto TSA within 24 hours of collection and then placed into Lim broth overnight. In addition, the pledget from the sample transport tube was placed in Lim broth, incubated and subcultured (10 µl) at 18-24 hours to a TSA plate. All plates were incubated in 5% CO_2 at 35°-37°C. If beta-hemolytic streptococcal colonies were observed, colonies were selected and confirmed using a streptococcal group serotyping method. The other swab was assayed in the STREP B OIA test within 24 hours of collection.

Of the 947 samples tested, 199 were positive by Lim broth, 121 (60.8%) were also positive by direct agar culture. 127 (63.8%) of the Lim broth positive samples were positive by the OIA method. Of the 748 Lim broth culture negative results, 745 (99.6) were negative by TSA and 698 (93.3%) were negative by the STREP B OIA test.

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The density of the GBS culture was judged by the growth pattern on the TSA blood agar plate. Growth in the first quadrant is graded 1+; second quadrant 2+; third quadrant 3+; and fourth quadrant 4+. Culture density data were available for 119/121 (98.3%) TSA culture positives and 119/199 (59.8%) of cultures positive by Lim broth. The sensitivity of the STREP B OIA assay for the degrees of culture density is as follows:

Culture Density	% OIA Positive
4+	100% (31/31)
3+	88 % (30/34)
2+	83 % (15/18)
1+	67 % (24/36)
Broth Only	34 % (27/79)

Broth only results were for samples that were negative on direct BAP culture but positive by either swab or pledget broth.

COMPARISON of STREP B OIA to Lim Broth Culture
947 SAMPLES

		OIA +	OIA -	
Lim Broth Culture	+	127	72	Sensitivity = 63.8% CI (56.7-70.5%)*
	-	50	698	Specificity = 93.3% CI (91.3-95.0%)*

COMPARISON of TSA Culture to Lim Broth Culture
947 SAMPLES

		TSA Culture +	TSA Culture -	
Lim Broth Culture	+	121	78	Sensitivity = 60.8% CI (53.7-67.6%)*
	-	3	745	Specificity = 99.6% CI (98.8-99.9%)*

* 95 % Confidence Interval

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

See sections G and H above.

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

AUG 19 1999

Roger C. Briden, Ph.D.
Director of Regulatory Affairs
BioStar, Inc.
6655 Lookout Road
Boulder, Colorado 80301

Re: K991828
Trade Name: Strep B OIA®
Regulatory Class: I
Product Code: GTY
Dated: May 28, 1999
Received: May 28, 1999

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

12.0 INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K991828

Device Name: STREP B OIA®

Indications For Use:

The BioStar® STREP B OIA® assay is an Optical ImmunoAssay (OIA) test for the rapid detection of group B streptococcal antigen directly from cervical and vaginal swabs from intrapartum maternity patients. The STREP B OIA assay is intended for use as an adjunct to culture, clinical observation and other information available to the physician.

(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 K991828

√ Prescription Use
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

OR

Over-The-Counter Use