NOV 1 8 2002 K022504

510(k) SUMMARY

July 26, 2002

Infectio Diagnostic Inc. IDI-Strep B™ assay

Submitted by: Infectio Diagnostic Inc.
2050, boul. René-Lévesque O, 4e étage
Sainte-Foy, Québec
Canada
G1V 2K8

Contact: Christian Choquet, PhD.

Name of Device:

Trade Name: IDI-Strep B™ Assay
Common Name: Group B streptococcus detection assay
Classification Name: Streptococcus spp. Serological reagents

Predicate Device: Thermo BioStar™ STREP B OIA®

Device Description:

Intended Use: IDI-Strep B™ assay is a qualitative *in vitro* diagnostic test for the rapid detection of Group B streptococcus (GBS) in vaginal/rectal specimens from intrapartum maternity patients. The test performed on the Smart Cycler® automated analyzer utilizes polymerase chain reaction (PCR) for the amplification of GBS DNA recovered from clinical samples and fluorogenic target-specific hybridization for the detection of the amplified GBS DNA.

IDI-Strep B™ assay can be used as the sole diagnostic information at the time of delivery for establishing GBS colonisation status of intrapartum maternity patients.

Test Description: GBS collected from a vaginal/rectal swab is resuspended in sample preparation buffer. A sample is added to the lysing tube containing glass beads. The proprietary procedure is based on a combination of chemical and physical (glass beads) action and takes less than 10 minutes. A sample of the lysate solution is then added to the tube containing the PCR master mix which has the GBS-specific primers used to amplify the GBS *cfb* gene, if present, and the internal control (IC) template. Finally, 25 µl is transferred to the reaction tube which is placed in the Smart Cycler® assay.

Amplified target DNA is detected with hybridization probes labeled with quenched fluorophores, i.e. molecular beacons. Different fluorophores are used for the detection of the GBS amplicon and for the detection of the IC amplicon. Their detection is independent of one another. Amplification of the internal control monitors for inhibitors potentially introduced with the clinical specimen and, in negative specimens, confirms the integrity of assay reagents. The interpretation of the data collected by the Smart Cycler® is made entirely by the diagnostic software of the Smart Cycler® instrument.

The amount of fluorescence at any given cycle, or following cycling, depends on the amount of specific amplicon present at that time. The Smart Cycler® instrument monitors simultaneously the fluorescence emitted by each beacon, interprets all data and at the end of the cycling program provides a final result.The operation of the Smart Cycler® instrument is based on the proprietary microprocessor-controlled I-CORE® (Intelligent Cooling/Heating Optical Reaction) module. Each

Smart Cycler® processing block contains 16 independently controlled, programmable I-Core® modules, each with one reaction site. Thermally optimized proprietary reaction tubes combined with the design of the I-CORE® modules allow very rapid temperature cycling and rapid amplification. Up to 6 Smart Cycler® processing blocks can be daisy-chained together, allowing simultaneous analysis of 96 discrete samples.

Substantial Equivalence:
The Infectio Diagnostic Inc. IDI-Strep B™ assay has been found to be substantially equivalent to the Thermo BioStar™ STREP B OIA® (K991828) and to broth culture. All assays detect GBS; the IDI-Strep B™ assay determines the presence of GBS through PCR amplification and fluorogenic target-specific hybridization detection; BioStar STREP B OIA® assay uses optical immunoassay technology for the detection of GBS antigen; broth culture uses culture characteristics for identification.

A multi-center study was conducted on 803 vaginal/rectal swab specimens collected from intrapatum maternity patients. The samples were evaluated with the IDI-Strep B™ assay and broth culture.

The results of the studies are summarized in the following table.

Summary of Clinical Trial Results

Overall Study

		IDI-Strep B™		
		Positive	Negative	Total
Culture technique	Positive	140[A]	9	149
	Negative	27[B]	626[C]	653
	Total	167	635	802

[A] Fourteen (14) specimens were initially culture negative but upon investigation were found to be culture positive; 1 of the 14 (specimen #898) had initially tested unresolved but upon re-testing gave a positive result; 3 specimens that were initially IDI-Strep B™ positive were retested because of invalid controls (positive and negative) and tested positive

[B] One (1) specimen that was initially positive with IDI-Strep B™ was retested because of an invalid control and re-tested positive

[C] Twelve (12) specimens that were initially negative with IDI-Strep B™ were retested because of an invalid control and all tested negative; 8 specimens that initially gave an unresolved result gave a negative result upon retesting

One specimen that gave an initially unresolved result remained unresolved upon retesting and was not included in the table above. Overall, 192 runs were conducted during the study. There were 5 invalid runs due to invalid controls. A total of 16 specimens were included in those runs.

Performances obtained for each investigational site and for the overall study

Investigational site	Clinical sensitivity (95% CI)[A]	Clinical specificity (95% CI)[A]	% unresolved specimens	% invalid runs
JGH, Montreal	93% (68%-100%)	93% (87%-96%)	3,0%	3,6%
MWH, Pittsburgh	88% (69%-97%)	100% (97%-100%)	0%	0%
ACH, Calgary	99% (93-100%)	97% (94%-98%)	0.2%	1.8%
WCH, Milwaukee	85% (54%-98%)	100% (98%-100%)	2.0%	4.7%
WHT, Houston	89% (67%-99%)	93% (82%-98%)	4.0%	4.2%
Overall study	94,.% (89.0%- 97.2%)	95.9% (94.0% - 97.3%)	1.2 %	2.6%

[A] Binomial 95% confidence intervals

The overall prevalence of the study population was 18.6 %, with the highest prevalence being observed in Pittsburgh (28.7%) and the lowest one in Montreal (9.1%). For the population tested in this study, this results in a negative predictive value of 98.6% (CI. 97.3% - 99.3%) and a positive predictive value of 83.8% (CI. 77.4% - 89.1%).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 8 2002

Infectio Diagnostic (I.D.I.) Inc.
c/o Ms. Judi Smith
Principal
Sienna Partners, L.L.C.
P.O. Box 103
Baldwin, MD 21013

Re: k022504
Trade/Device Name: IDI- Strep B™ Assay
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus Spp. Serological Reagents
Regulatory Class: Class I
Product Code: NJR
Dated: October 23, 2002
Received: October 24, 2002

Dear Ms. Smith:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K022504

Device Name: IDI Strep B

Indications For Use:

Intended Use: IDI-Strep B™ assay is a qualitative *in vitro* diagnostic test for the rapid detection of Group B streptococcus (GBS) DNA in vaginal/rectal specimens from prepartum or intrapartum women. The test performed on the Smart Cycler® automated analyzer utilizes polymerase chain reaction (PCR) for the amplification of a *cfb* gene sequence of GBS recovered from clinical samples and fluorogenic target-specific hybridization for the detection of the amplified DNA.

IDI-Strep B™ assay can be used to establish GBS colonisation status of prepartum and intrapartum women.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie L. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K022504

Prescription Use ✓ OR Over-The-Counter Use

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