K971522

MAR - 3 1998

510(k) Summary
Abbott TestPack® Plus™ Strep A with OBC® II

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The following information as presented in the Premarket Notification [510(k)] for Abbott TestPack® Plus™ Strep A with On Board Controls (OBC®) II constitutes data supporting a substantially equivalent determination.

Substantial equivalence has been demonstrated between TestPack Plus Strep A with OBC II and the results obtained through isolation of Group A Strep colonies on sheep blood agar medium followed by a serological grouping of presumptive Group A Strep.

TestPack Plus Strep A with OBC II is a rapid immunoassay for the qualitative detection of Group A Streptococcal antigen from throat swab specimens or confirmation of presumptive Group A Strep colonies recovered from culture.

The intended use of both is for the qualitative detection of *Streptococcus pyogenes*. Both can be used with throat swab specimens. TestPack Plus Strep A with OBC II detects Strep A specific antigen, whereas, culture and confirmation by typing identify growth of the *Streptococcus pyogenes* organisms. TestPack Plus Strep A with OBC II can be used for both the qualitative identification of Group A Strep antigen and the confirmation of suspect colonies from culture, whereas, culture and confirmation by typing can only be used for the qualitative detection of *Streptococcus pyogenes* organisms. TestPack Plus Strep A with OBC II utilizes an internal on board control system consisting of six control features, however, culture does not contain any internal controls. TestPack Plus Strep A with OBC II requires processing of the throat swab specimen, however, culture does not require processing of the throat swab specimen.

Clinical testing was performed on 445 throat swabs collected at five U.S. clinical sites from patients seeking medical attention for pharyngitis. Each swab was used to inoculate 5% Sheep Blood Agar (SBA) and Strep Selective Sheep Blood Agar (SSA) culture plates within 30 minutes of collection. The culture plates were aerobically incubated at 35 to 37°C. Suspect beta-hemolytic colonies were confirmed as Group A Strep by a latex agglutination test. When compared to SBA culture, TestPack Plus Strep A with OBC II assay demonstrated a sensitivity of 92.9% at End of Assay (EOA) and 94.6% at 10 minutes after specimen addition, a specificity of 97.9% at EOA and 97.0% at 10 minutes after specimen addition, and an agreement of 96.6% at EOA and 96.4% at 10 minutes after specimen addition for all sites combined. When compared to SSA culture, TestPack Plus Strep A with OBC II assay demonstrated a sensitivity of 90.4% at EOA and 92.2% at 10 minutes after specimen addition, a specificity of 97.9% at EOA and 97.0% at 10 minutes after specimen addition, and an agreement of 96.0% at EOA and 95.7% at 10 minutes after specimen addition for all sites combined.

In conclusion, these data demonstrate that the TestPack Plus Strep A with OBC II assay is as safe and effective as, and is substantially equivalent to the results obtained through isolation of Group A Strep colonies on SBA culture plates or SSA culture plates.

Prepared and Submitted April 24, 1997 by:

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MAR - 3 1998

Re: K971522
Trade Name: Abbott TestPack® PLUS™ Strep A with On Board Controls (OBC®) II
Regulatory Class: I
Product Code: GTZ
Dated: December 18, 1997
Received: December 19, 1997

Dear Ms. LeMieux:

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 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

510(k) Number (if known): K971522

Device Name: Abbott TestPack® Plus™ Strep A with On Board Controls (OBC®) II

Indication For Use:

21 CFR 866.3740 Streptococcus spp. serological reagents.
"*Streptococcus* spp. serological reagents are devices that consist of antigen and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on skin), urinary tract infections, rheumatic fever, and kidney diseases."

Abbott TestPack Plus Strep A with On Board Controls (OBC) II is a rapid immunoassay for the qualitative detection of Group A Streptococcal (Group A Strep) antigen in throat swab specimens from patients with suspected Group A Strep associated pharyngitis and for confirmation of presumptive Group A Strep colonies isolated on culture plates.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971522