K972182

AUG 13 1997

510(k) Summary
Abbott STREP A Controls

Summary of Safety and Effectiveness Information Supporting a Substantial Equivalent Determination

The following information as presented in the PreMarket Notification (510(k) for Abbott STREP A Controls) constitutes data supporting a substantially equivalent determination.

Substantial equivalence has been demonstrated between Abbott STREP A Controls and Abbott STREP A Controls, K922490.

The Abbott STREP A Controls, K965252 is the same as Abbott STREP A Controls, K922490. The controls are intended for use as external controls to monitor substantial reagent failure and procedural errors in Abbott Rapid Immunoassays for the qualitative detection of Group A Streptococcal antigen . Studies were performed to demonstrate that two lots of Strep A positive control gave 100% correct results across each of the Abbott Rapid Group A Strep Immunoassays (three lots each). Four lots of Strep A negative controls were tested and gave 100% correct results across three lots of TestPack Plus Strep A with OBC.

In conclusion, these data demonstrate that the Abbott STREP A Controls is as safe and effective and is substantially equivalent to Abbott STREP A Controls, K922490.

Prepared and Submitted:

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RELATIVE LIMIT OF DETECTION OF ABBOTT RAPID STREP A ASSAYS

Purpose:
To determine the Relative Limit of Detection for the Abbott Rapid Strep A assays: TestPack Strep A (TPSA), List 01301, TestPack Plus Strep A (TP+SA), List 03A59, TestPack Plus Strep A with On Board Controls (TP+SA-OBC), List 01B53, and the upcoming TestPack Plus Strep A with On Board Controls II (TP+SA-OBC II), List 05C63.

Method:
The Relative Limit of Detection was determined by identifying the dilution levels of Strep A Stock that consistently produced low level positive results on three lots of reaction discs for each assay. Strep A Stock is a suspension of phenol-killed Strep A organisms used to make the current external Positive Control, List 03078. This suspension of phenol-killed organisms is prepared at an absorbance reading (A630) of 0.52 to 0.56.

Two lots of the Strep A Stock were used in this study. Initial dilutions of 1:10, 1:100, 1:1000 and 1:10000 were prepared using a phosphate buffer as diluent. Both the buffer and the Strep A Stock are currently used in the manufacture of Positive Control. To determine the Relative Limit of Detection, 100 uL of the dilutions were used to seed dacron swabs. This volume simulates a swab dipped into Positive Control as required by the control package insert. The swabs were extracted for one minute and tested on three lots of reaction discs on each of the four assays. Two replicates of each dilution were assayed. The results were visually read at EOA for all assays. Additional intermediate dilutions were needed to determine the Relative Limit of Detection for TPSA and TP+SA-OBC II, 1:667 for both assays and 1:500 for TP+SA-OBC II (see Table 1).

Results:
Refer to Table 1 which shows the test results for swab samples seeded with 1:10, 1:100, 1:500, 1:667, 1:1,000, 1:2000 and 1:10,000 dilutions from two lots of stock Strep A suspensions.

For TPSA, the greatest dilution which consistently produced positive results was 1:667; that is, dilutions greater than 1:667 did not consistently produce positive results for the two lots of Strep A suspensions and for the three lots of TPSA used.

For TP+SA and TP+SA OBC, the greatest dilution which consistently produced positive results was 1:1000; that is, dilutions greater than 1:1000 did not consistently produce positive results for these two assays.

For TP+SA OBC II, the greatest dilution which consistently produced positive results was 1:500; that is, dilutions greater than 1:500 did not consistently produce positive results for this assay.

Summary:
These data suggest the manufacture of a "new" positive control made at approximately ten times (one log above) the relative limits of detection for the four assays . This corresponds to a 1:100 dilution of the stock Strep A suspension (refer to Table 2).

* Faxed to FDA on 4-16-97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 13 1997

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Re: K972182
Trade Name: Abbott STREP A Controls
Regulatory Class: I
Product Code: MJZ
Dated: May 28, 1997
Received: May 29, 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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): K972182

Device Name: Abbott STREP A Controls

Indications For Use:

Abbott STREP A Controls are qualitative control materials intended for use in test systems to monitor substantial reagent failure and procedural errors. Specifically, Abbott STREP A Controls are intended for use as external controls in Abbott Rapid Immunoassays for the qualitative detection of Group A Streptococcal antigen.

(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 Clinlcal Laboratory Devices
510(k) Number 972182