K982362

NOV 18 1998

Section II

510(k) Summary

510(k) Summary
Abbott TestPack® Plus™ *H. pylori*

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The following information as presented in the Premarket Notification [510(k)] for the Abbott TestPack Plus *H. pylori* assay constitutes data supporting a substantially equivalent determination.

Abbott TestPack Plus *H. pylori* is a rapid, visually read, qualitative immunoassay for the detection of human IgG antibodies specific to *Helicobacter pylori* in human serum, plasma, or whole blood. The assay is intended for use by health professionals as an aid in the diagnosis of *H. pylori* infection in patients with clinical signs and symptoms of gastrointestinal disease. There are two kit configurations associated with the Abbott TestPack Plus *H. pylori* assay, one where the intended use is for testing serum, plasma, venous whole blood, and fingerstick whole blood specimens and a second where the intended use is for testing whole blood specimens collected by fingerstick or venipuncture.

Substantial equivalence has been demonstrated between the Abbott TestPack Plus *H. pylori* assay and the HM-CAP™ *Helicobacter pylori* Enzyme Immunoassay for the detection of *H. pylori* specific IgG antibodies. The intended use of the HM-CAP assay is for the qualitative detection of IgG antibody to *H. pylori* in human serum and it is used as an adjunct in the diagnosis of infection by *H. pylori*.

Fresh serum specimens were obtained from 107 symptomatic patients undergoing endoscopic examination at two clinical sites. Forty nine (49) specimens were tested at one site, of which four were excluded from the analysis because the biopsy test results were indeterminate for *H. pylori* infection. The sensitivity and specificity were 90.9% (10/11) (95% C.I. of 58.7% to 99.8%) and 76.5% (26/34) (95% C.I. of 58.8% to 89.3%), respectively. The presence of *H. pylori* specific IgG antibodies in all eight TestPack

positive and biopsy negative specimens from this site were detected by the HM-CAP assay. Fifty eight (58) specimens were tested and analyzed at the second site resulting in a sensitivity and specificity of 70.8% (17/24) (95% C.I. of 48.9% to 87.4%) and 88.2% (30/34) (95% C.I. of 72.6% to 96.7%), respectively. The presence of *H. pylori* specific IgG antibodies in all four TestPack positive and biopsy negative specimens from this second site was detected by the HM-CAP assay. Similarly, the absence of *H. pylori* specific IgG antibodies in two of seven TestPack negative and biopsy positive specimens was observed by the HM-CAP assay.

A comparison was made with the TestPack assay to biopsy and the HM-CAP assay using 135 previously characterized serum specimens. (Refer to Table 1.) Two of the 135 specimens were HM-CAP indeterminate and not used in the TestPack to HM-CAP analysis. (Refer to Table 2.)

Table 1
Abbott TestPack Plus *H. pylori*
Compared to Biopsy

n	Agreement	Sensitivity (95% C.I.)	Specificity (95% C.I.)
135	92.0% (124/135)	92.3% (96/104) (85.4% to 96.6%)	90.3% (28/31) (74.3% to 98.0%)

Table 2
Abbott TestPack Plus *H. pylori*
Compared to HM-CAP

n	Relative Agreement	Relative Sensitivity (95% C.I.)	Relative Specificity (95% C.I.)
133	94.0% (125/133)	95.0% (96/101) (88.8% to 98.4%)	90.6% (29/32) (75.0% to 98.0%)

In conclusion, these data demonstrate that the Abbott TestPack Plus *H. pylori* assay is as safe and effective as, and is substantially equivalent to, the HM-CAP *Helicobacter pylori* Enzyme Immunoassay.

Prepared and Submitted July 2, 1998 by:
Abbott Laboratories
Irene Powers
Regulatory Section Leader
ADD Regulatory Affairs
1-847-937-1998
200 Abbott Park Road
Abbott Park, IL 60064-3537

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 1998

Irene Powers
Section Leader - Devices
ADD Regulatory Affairs
Dept. 9V6, Building AP31
200 Abbott Park Road
Abbott Park, Illinois 60060-3537

Re: K982362/S1
Trade Name: Abbott TestPack® Plus™ *H.pylori*
Regulatory Class: I
Product Code: LYR
Dated: September 24, 1998
Received: September 25, 1998

Dear Ms. Powers:

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.

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 (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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982362

Device Name: Abbott TestPack® Plus™ *H. pylori*

Indications For Use:

The Abbott TestPack® Plus™ *H. pylori* assay is a rapid, visually read, qualitative immunoassay for the detection of human IgG antibodies specific to *Helicobacter pylori* in serum, plasma, and whole blood specimens from symptomatic adults.

Reference:

1. McGuigan JE. Peptic Ulcer and Gastritis. In: *Harrison's Priniciples of Internal Medicine, 12th Edition*, New York: McGraw-Hill, 1991:1229–1248.

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982362

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)