DEC 17 1998

K983255

A. 510(k) Summary

Identification Information

Submitter's Information:

Submitter's Name and Address:

Meridian Diagnostics, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

Phone Number: 1-800-543-1980

Contact Person: Allen D. Nickol, PhD
Director of Clinical and Regulatory Affairs

Date Summary Prepared: September 14, 1998

Name of Device: Premier Platinum HpSA

Classification Name:
Campylobacter pylori, 83LYR

Predicate Equivalent Device:
Meretek UBT

Description of Device:
The **Premier Platinum HpSA** test utilizes polyclonal anti-*H. pylori* capture antibody adsorbed to microwells. Diluted patient samples and a peroxidase conjugated polyclonal antibody are added to the wells and incubated for one hour at room temperature. A wash is performed to remove unbound material. Substrate is added and incubated for ten minutes at room temperature. Color develops in the presence of bound enzyme. Stop solution is added and the results are interpreted visually or spectrophotometrically.

Intended Use:
The Premier Platinum HpSA enzyme immunoassay (EIA) is an *in vitro* qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection, and to monitor response during and post-therapy in adult patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.

Comparison with Predicate Device:

The following comparison of the use, technology, function and performance supports the Statement of Equivalence between the **Premier Platinum HpSA** test and the Urea Breath Test (UBT). The differences in technology do not raise additional concerns regarding safety and effectiveness. Safety and effectiveness are demonstrated to be substantially equivalent.

	Premier Platinum HpSA	Urea Breath Test
Intended Use	Detection of *H. pylori* antigens in patient stool	Detection of *H. pylori* associated urease activity in breath specimens
Results	Qualitative	Qualitative
Specimen Required	Stool	Before and after breath specimens
Technology	Sandwich Enzyme Immunoassay	*H. pylori* urease catalyzed conversion of $^{13C\text{-urea}}$ to ^{13CO2} and ammonia. ^{13CO2} is detected by GC-mass spectroscopy
Level of Skill Required	Laboratory Technician	Nurse or physician to administer test and collect specimens. G/C Mass Spec and certified lab / technician to perform analysis.
Function	1. Specimen diluted 1/3 and added to well containing rabbit anti-H. *pylori* capture Ab. 2. One drop HRP-conjugated detection Ab added. 3. Incubation 1 hr at room temperature. 4. Wash 5 times. 5. Add 2 drops substrate. 6. Incubate 10 minutes at room temperature. 7. Add one drop stop solution and read visually or spectrophotometrically	1. Baseline breath specimens are taken in duplicate. 2. Pudding and urea solution are ingested. 30 minute metabolism. 3. Test breath specimens are taken in duplicate. 4. Samples are mailed in for analysis by licensed laboratory. 5. Results reported as ratio of Delta over Baseline (DOB)
Interpretation	Pos/Neg read visually or spectrophotometrically. Fixed cut-off 0.140 single wavelength (450nm) or 0.100 dual wavelength (450-630nm)	DOB ≥ 2.4: Positive DOB < 2.4: Negative
Performance vs. Reference Methods		
Sensitivity	94.7% (74.0-99.0%)	85.0% (62.1-96.8%)
Specificity	96.1% (88.9-99.2%)	96.1% (88.9-99.2%)
Correlation	95.8% (89.6-98.8%)	93.8% (86.9-97.7%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 1998

Allen D. Nickol, Ph.D.
Director of Clinical and Regulatory Affairs
Meridian Diagnostics, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

Re: K983255
Trade Name: Premier Platinum HPSA
Regulatory Class: I
Product Code: LYR
Dated: December 1, 1998
Received: December 2, 1998

Dear Dr. Nickol:

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

E. Indications for Use Statement

510(k) Number (if known): K983255

Device Name: Premier Platinum HpSA

Indications For Use:

The Premier Platinum HpSA enzyme immunoassay (EIA) is an *in vitro* qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection, and to monitor response during and post-therapy in adult patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.

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 K983255

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)