OCT 29 1997 K972352

510(k) SUMMARY

The MERETEK UBT® Breath Test for Detection of *H.pylori*

A. Applicant's Name, Address, Contact Person, and Date of Preparation

MERETEK*diagnostics*, inc.
618 Grassmere Park Drive
Suite 20
Nashville, Tennessee 37211

Please direct any requests for information to:

Mr. Kerry C. Bush
Vice President and Chief Operating Officer
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Suite 20
Nashville, Tennessee 37211

Phone: (615) 333-6336
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This 510(k) summary was prepared October, 1997.

B. Device Name and Classification

Trade Name of the Device:
The MERETEK UBT® Breath Test for *H.pylori*

Common Name of the Device:
Breath Test for *Helicobacter pylori*; UBT

Classification:
Name: *Campylobacter pylori* (presence)
Note: *Campylobacter pylori* was officially renamed *Helicobacter pylori* in 1989.
Class: I

C. The Predicate Device

Since this Premarket Notification is for labeling modification to a cleared device (K952220), the predicate device is the device itself: The MERETEK UBT® Breath Test for Detection of *H. pylori*.

D. Description of the Device

The device is a combination kit diagnostic drug/device composed of the following principle components:

Test Meal (of approximately 220 calories)
Pranactin Diagnostic Drug Dosage
Sterile Water
Breath Bag
Evacuated Breath Specimen Collection Tubes

Principle of the Test

In the MERETEK UBT® Breath Test for *H. pylori*, 125 mg of reconstituted ^{13}C-urea is ingested by the patient. In the presence of urease associated with gastric *H. pylori*, ^{13}C-urea is decomposed to $^{13}CO_2$ and NH_4^+ according to the following equation:

$$\underset{^{13}\text{C-urea}}{(NH_2)_2{}^{13}CO} + H_2O + 2H^+ \xrightarrow{HpUrease} {}^{13}CO_2 + 2NH_4^+$$

The $^{13}CO_2$ is absorbed in the blood, then exhaled in the breath. This results in an increase in the ratio of $^{13}CO_2$ to $^{12}CO_2$ in a TEST breath sample compared to a BASELINE sample taken before the Pranactin® solution was consumed. Analysis of the breath samples is performed by Gas Isotope Ratio Mass Spectrometry ("GIRMS") at Meretek's clinical laboratories or at other qualified laboratories licensed by MERETEK*diagnostics,* inc.

E. Intended Use

The MERETEK UBT® Breath Test Collection Kit is intended for use in the qualitative detection of urease associated with *Helicobacter pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *Helicobacter pylori* infection in adult patients. The test may be used for monitoring treatment if used at least four weeks following completion of therapy. For these purposes, the system utilizes a Gas Isotope Ratio Mass Spectrometer ("GIRMS") for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples.

For administration by health care professionals. To be administered under a physician's supervision.

F. Technological Characteristics of the Device and the Predicate Device

The technological characteristics of the subject device are the same as the predicate device.

G. Clinical Testing

Experimental Design

The method comparison data presented here were collected from two (2) independent double blind clinical field trials which involved treatment of *H.pylori* infection. The studies included 499 adult patients with duodenal ulcer disease at 75 clinical sites in the United States. Patients were tested for *H.pylori* infection initially (using histopathology, microbiological culture, CLOtest®, and the MERETEK UBT®), and at various post-treatment intervals throughout the study (using histopathology, microbiological culture, and the MERETEK UBT®). In these clinical trials patients were treated with various

combinations of clarithromycin, omeprazole and placebo. Note, however, that there is no evidence that differing treatment regimens affect the performance of the MERETEK UBT®.

Results

Method comparison results are presented in two-way contingency tables. In tables 1, 2 and 3, the MERETEK UBT® Breath Test results are compared with the CLOtest®, histology and with the combined endoscopic method results for the initial patient visit. In table 4, the MERETEK UBT® Breath Test results are compared with the combined endoscopic method results (histology and culture) for the post-treatment visits which occurred four weeks or more after end of treatment. The exact binomial distribution was used to calculate the lower and upper limits of the 95% confidence intervals of the performance statistics. The confidence intervals are entered in parentheses following the point estimate of the statistic.

Performance Characteristics for Initial Diagnosis

Table 1. Comparison with CLOtest® for Initial Visit

	Meretek UBT® Breath Test results		
CLOtest®	**positive**	**negative**	**Total**
positive	397	31	428
negative	1	16	17
Total	398	47	445

Relative sensitivity: 92.8 % [95% CI: (89.9,95.0)]
Relative specificity: 94.1 % [95% CI: (71.3,99.9)]

Table 2. Comparison with histology for Initial Visit

	Meretek UBT® Breath Test results		
Histology	**positive**	**negative**	**Total**
positive	394	20	414
negative	3	27	30
Total	397	47	444

Relative sensitivity: 95.2 % [95% CI: (92.6,97.0)]
Relative specificity: 90.0 % [95% CI: (73.5,97.9)]

Table 3. Comparison with combined endoscopic methods for Initial Visit (Combined endoscopic methods used were CLOtest®, histology and culture per DAIDP guidelines for pre-treatment diagnosis.)

	Meretek UBT® Breath Test results		
Endoscopy	**positive**	**negative**	**Total**
positive	395	20	415
negative	3	26	29
Total	398	46	444

Sensitivity: 95.2 % [95% CI: (92.6,97.0)]
Specificity: 89.7 % [95% CI: (72.6,97.8)]

Performance Characteristics for Post-Treatment Monitoring

Table 4. Comparison with combined endoscopic methods * for Post-Treatment Visits (four weeks or more after End of Treatment (EOT))

	Meretek UBT® Breath Test results							
	1 Month EOT		3 Months EOT		6 Months EOT		1-6 Months Combined	
Endoscopy	**pos**	**neg**	**pos**	**neg**	**pos**	**neg**	**pos**	**neg**
positive	187	6	123	8	91	5	401	19
negative	5	97	4	87	2	80	11	264
Sensitivity	96.9		93.9		94.8		95.5	
(95% CI)	(93.4,98.8)		(88.3,97.3)		(88.3,98.3)		(93.0,97.2)	
Specificity	95.1		95.6		97.6		96.0	
(95% CI)	(88.9,98.4)		(89.1,98.8)		(91.5,99.7)		(93.0,98.0)	

*** Combined endoscopic methods used were histology and culture per DAIDP guidelines for post-treatment monitoring)**

Please note that the post-treatment performance characteristics at 1, 3 and 6 months after therapy are not statistically different. Therefore, the single best estimates of sensitivity and specificity are presented in the 1-6 Months Combined column.

Negative Predictive Value (NPV) for Post-Treatment Monitoring

Given the post-treatment sensitivity (95.5%) and specificity (96.0%) observed in these studies, and assuming a treatment efficacy of 90% (10% prevalence of residual *H.pylori* infection), the NPV of the MERETEK UBT® is greater than 99%. When efficacy of treatment drops to 50%, the NPV is still greater than 95%.

H. Adverse Events

There were no adverse events related to the use of the MERETEK UBT® reported during the clinical trials.

I. Conclusion

The MERETEK UBT® is safe and effective for its intended use in the qualitative detection of urease associated with *Helicobacter pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *Helicobacter pylori* infection in adult patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 29 1997

Claudia T. Hitchcock
President & Chief Executive Officer
Meretek Diagnostics, Inc.
618 Grassmere Park Drive
Suite 20
Nashville, TN 37211

Re: K972352
Trade Name: The Meretek UBT™ Breath Test for *Helicobacter pylori*
Regulatory Class: II
Product Code: MSQ
Dated: September 2, 1997
Received: September 3, 1997

Dear Mr. Bush:

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 requirement, 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

X. STATEMENT OF INDICATIONS FOR USE

Device Name:

MERETEK UBT™ Breath Test For *H.pylori*

Indications for Use:

The MERETEK UBT™ Breath Test Collection Kit is intended for use in the qualitative detection of urease associated with *Helicobacter pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *Helicobacter pylori* infection in adult patients. For this purpose, the system utilizes a Gas Isotope Ratio Mass Spectrometer ("GIRMS") for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples.

For administration by health care professionals. To be administered under a physician's supervision.

Prescription Use: Yes

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972352

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The Counter Use ____

(Optional Format 1-2-96)