

XI. SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

The following information as presented in the Premarket Notification [510(k)] for the QuickVue One-Step H. pylori II Test constitutes data supporting a substantially equivalent determination.

Product:

QuickVue® One-Step H. pylori II Test

Manufacturer:

QUIDEL Corporation
10165 McKellar Court
San Diego, California 92121

Device Classification:

The device, QuickVue One-Step H. pylori II Test, is similar to other FDA-cleared devices used for the qualitative detection of IgG antibodies to *Helicobacter pylori* directly from clinical specimens. These tests are used to aid in the diagnosis of disease caused by bacteria belonging to the genus *Campylobacter* and provide epidemiological information on these diseases (21 CFR 866.3110). *Helicobacter pylori* (formerly *Campylobacter pylori*) has not yet been classified by the FDA separately from *Campylobacter*.

The Food and Drug Administration has proposed that serological tests systems for the identification of *Helicobacter pylori* be classified as Class I.

Intended Use:

The QuickVue One-Step H. pylori II Test is intended for the rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in human serum, plasma and whole blood as an aid in the diagnosis of *H. pylori* infection in patients with clinical signs and symptoms of gastrointestinal disease. The test is intended for use by health care professionals.

Physiologic Basis for the Test:

Helicobacter pylori (formerly *Campylobacter pyloridis* and *Campylobacter pylori*) is implicated in the etiology of a variety of gastrointestinal diseases, including non-ulcer dyspepsia, duodenal and gastric ulcer, and active and chronic gastritis. Recent studies also suggest an association of *H. pylori* infection with stomach cancer; the role of *H. pylori* and the factors involved in the development of these diseases is still under investigation.

Symptomatic patients with *H. pylori* are said to be infected, whereas asymptomatic patients with *H. pylori* are said to be colonized. Although infections are persistent, several treatment regimens using antibiotics in combination with bismuth compounds have been shown to be effective in treating active *H. pylori* infection. Successful eradication of *H. pylori* is associated with clinical improvement in patients with chronic active gastritis, gastric ulcer and duodenal ulcer, providing further evidence for a link between *H. pylori* infection and these diseases.

Principle of the Test:

The QuickVue One-Step *H. pylori* II Test, a lateral-flow immunoassay using patented technology, employs a monoclonal antibody and purified *H. pylori* antigen. Shortly after addition of the sample to the Test Cassette, a blue procedural Control Line will appear in the Result Window. If *H. pylori*-specific IgG is present in the sample, a faint-to-dark red Test Line will also appear in the Result Window. The result is read at 5 minutes. If no blue procedural Control Line develops, the result is considered invalid.

Safety and Effectiveness:

Substantial equivalence has been demonstrated between the QuickVue One-Step *H. pylori* II Test and biopsy for the detection of *H. pylori*-specific IgG antibodies. Using over 300 clinical specimens obtained from symptomatic and asymptomatic patients undergoing endoscopic examination, a comparison of the QuickVue One-Step *H. pylori* II Test to biopsy and to a commercially available EIA was conducted in a multi-center field study. An agreement exceeding 90% was observed.

Physician's Office Laboratory studies were also conducted to show that doctor's office personnel with diverse educational backgrounds and work experience could perform the test accurately and reproducibly. Testing was performed at three geographically distinct sites in the United States. The results obtained at each site agreed 100% with the expected results.

Conclusion:

In conclusion, these studies demonstrate the substantial equivalence of the QuickVue One-Step *H. pylori* II Test to existing products already marketed in the detection of *H. pylori* specific IgG antibodies. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG - 4 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Robin Weiner
Vice President
Clinical and Regulatory Affairs
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

Re: K991747
Trade Name: QuickVue® One-Step *H. Pylori* II Test
Regulatory Class: I
Product Code: LYR
Dated: May 20, 1999
Received: May 21, 1999

Dear Ms. Weiner:

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.

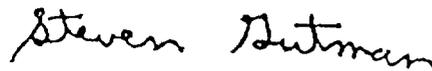
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XIII. Indications for Use (Separate Page):

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510(k) Number (if known): _____

Device Name: QuickVue® One-Step H. pylori II Test

Indications for Use:

The QuickVue One-Step H. pylori II Test is intended for the rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in human serum, plasma and whole blood as an aid in the diagnosis of *H. pylori* infection in patients with clinical signs and symptoms of gastrointestinal disease. The test is intended for use by health care professionals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The Counter Use _____

Woody Dubois

(Division Sign-off)
Division of Clinical Laboratory Devices

510(k) Number K991747