K991697

DEC 21 1999

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K991697.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Trinity Biotech, plc
IDA Business Park
Bray
County Wicklow, Ireland

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Trinity Biotech, plc
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Summary Date: November 5, 1999

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): Uni-Gold™ *H. pylori* test kit

Name (usual): *Helicobacter pylori* serological reagents

Classification: 21 CFR 866.3110, Class I, LYR

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

The Uni-Gold *H. pylori* test kit is substantially equivalent to the Quidel QuickVue One-Step *H. pylori* Test (QuickVue), Quidel Corporation, San Diego, CA. The Uni-Gold *H. pylori* test kit is identical, or similar to, its predicate in terms of: intended use, antibodies detected, technology/methodology, testing matrices, and result interpretation.

Description of Device (21 CFR 807.92 (a)(4))

As the sample flows laterally through the membrane, the specific antibody binding-protein dye conjugate binds to the human immunoglobulins in the sample. If the sample contains IgG antibodies to *H. pylori*, the complex binds to the antigens on the solid phase of the device's test region producing a red/pink (red) line. In the absence of *H. pylori* antibodies, no line appears in the test region of the device. A procedural-functional control is built in to each device. As the sample migrates across the control region, the appearance of a red line at the control region indicates correct procedure and a functional device.

Intended Use (21 CFR 807.92 (a)(5))

The Trinity Biotech Uni-Gold™ *H. pylori* assay is intended for the rapid *in vitro* qualitative detection of IgG antibodies to *Helicobacter pylori* (*H. pylori*) in adult human serum, plasma, or whole blood as an aid in the diagnosis of *H. pylori* infection in patients with clinical signs and symptoms of gastrointestinal disease.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between the Uni-Gold *H. pylori* test kit and the predicate device (QuickVue) follows.

Similarities Between Uni-Gold™ *H. pylori* test kit and QuickVue

CHARACTERISTIC	UNI-GOLD™ *H. PYLORI*	QUICKVUE
Intended Use	immunoassay for the rapid qualitative detection of IgG *Helicobacter pylori* antibodies in adult human whole blood, serum, or plasma. The test is intended for professional use in physicians' offices and hospital laboratories as an aid in the diagnosis of *H. pylori* infection in patients with clinical signs and symptoms of gastrointestinal disease.	immunoassay for the rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in human serum, plasma, or 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 professional/laboratory use.
Antibodies Detected	*Helicobacter pylori*	*Helicobacter pylori*
Methodology/Technology	As the sample flows laterally through the membrane, the specific antibody binding-protein dye conjugate binds to the human immunoglobulins in the sample. If the sample contains IgG antibodies to *H. pylori*, the complex binds to the antigens on the solid phase of the device's test region producing a red/pink (red) line. In the absence of *H. pylori* antibodies, no line appears in the test region of the device. A procedural-functional control is built in to each device. As the sample migrates across the control region, the appearance of a red line at the control region indicates correct procedure and a functional device.	Sample flows through a pad containing purified *H. pylori* antigen coupled to red beads and blue control beads. If the sample contains *H. pylori* specific IgG antibody, it will bind to the antigen coupled to the red beads, which, in turn, will bind to a monoclonal anti-human IgG antibody spotted on the membrane. As the *H. pylori* antigen-antibody complex is captured, a red Test Line will appear in the Result Window. A blue Procedural Control Line will also appear if proper fluid volume entered the device and capillary flow occurred. If *H. pylori* IgG antibody is not present, or is present at very low levels, only a blue Control Line will be visible.
Testing Matrices	whole blood, serum, plasma	whole blood, serum, plasma
Result Interpretation	positive or negative for *H. pylori* antibodies	positive or negative for *H. pylori* antibodies
Assay Read Time	10 minutes	10 minutes

Differences Between Uni-Gold *H. pylori* Test Kit and QuickVue

CHARACTERISTIC	UNI-GOLD *H. PYLORI*	QUICKVUE
Assay Procedure	1 drop of sample followed by 3 drops of wash	3 drops of sample
Sample Volume	30 µL	>100 µL
Storage Temperature	2-27° C	15-30° C

Brief Discussion of Nonclinical Data (21 CFR 807.92(b)(1))

Studies were conducted to evaluate cross reactivity, effects of hematocrit, sample stability, and test performance in various matrices (whole blood [fingerstick and venous], serum, and plasma).

No cross reactivity was observed with the testing of the following organisms: *Campylobacter jejuni, Campylobacter coli, Campylobacter fetus,* and *Escherichia. coli,* and *Borrelia burgdorferi* antibodies (Lyme disease positive samples). Further, there was no effect from the addition of very high levels of bilirubin, albumin, and hemoglobin.

The Uni-Gold™ *H. pylori* assay provided accurate results with hematocrits ranging from 39% to 53%.

Serum and plasma samples may be assayed when stored at 2-8°C for up to three days, and when stored frozen at -20°C for longer intervals. Also, there were equivalent results in whole blood, serum, and plasma matrices.

Brief Discussion of Clinical Data (21 CFR 807.92 (b)(2)

The clinical sensitivity and specificity (accuracy) of the Uni-Gold™ *H. pylori* test kit was determined by the analysis of 348 clinical samples (164 positive and 184 negative) at three independent sites (USA, Canada, and Sweden). The clinical trials were performed on patients of mixed populations of race, sex, and age who presented with various gastrointestinal symptoms.

All patients underwent venipuncture for detection of antibodies to *H. pylori* by the Uni-Gold™ *H. pylori* test kit, and a commercially available ELISA kit, as well as gastric biopsy for culture and histology for the detection of *H. pylori* infection. Biopsy "positive" was defined as culture and histology positive or culture positive, and biopsy "negative" was defined as negative for both culture and histology, or negative for culture. Biopsy results were considered the gold standard reference results for the detection of active *H. pylori* infection. The results are summarized below.

Uni-Gold™ *H. pylori* Test Kit Results vs Biopsy Results

n = 348 samples		Biopsy	Results
		+	-
Uni-Gold™ *H. pylori*	+	136	32
	-	28	152
Reference Totals		164	184

The data demonstrated the Uni-Gold™ *H. pylori* test kit correctly identified 136 of the 164 biopsy-positive samples for a sensitivity of 83%, and correctly identified 152 of 184 biopsy-negative samples for a specificity of 83%. The overall accuracy was 83%.

Uni-Gold™ *H. pylori* test kit Vs Biopsy In Conjunction with ELISA

ELISA results were used to evaluate the 60 discrepant results (28 false negative and 32 false positive) between the Uni-Gold *H. pylori* test kit and biopsy. The ELISA method detects the presence of human IgG antibodies to *H. pylori*, and the ELISA testing was performed on all samples (* sample volume permitting).

> * only 52 of the 60 results are reported as there was either insufficient sample for ELISA testing, or ELISA results were inconclusive.

The data indicate that, of the 52 available results, 20 were found to be positive by both the Uni-Gold™ *H. pylori* test and ELISA, and five were found to be negative by both methods.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The studies demonstrated the substantial equivalence of the Uni-Gold™ *H. pylori* test kit to existing products already marketed. Cross-reactivity studies confirmed the specificity of the assay, and clinical studies confirmed the assay's accuracy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

Trinity Biotech, plc
c/o Ms. Erika B. Ammirati, RAC, MT(ASCP)
Ammirati Regulatory Consulting
575 Shirlynn Court
Los Altos, California 94022

Re: K991697
Trade Name: Uni-Gold™ *H. pylori*
Regulatory Class: I
Product Code: LYR
Dated: November 5, 1999
Received: November 8, 1999

Dear Ms. Ammirati:

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

510(k) Number (if known): K991697

Device Name: Uni-Gold™ *H. pylori*

Indications For Use:

The Trinity Biotech Uni-Gold™ *H. pylori* assay is intended for the rapid *in-vitro* qualitative detection of IgG antibodies to *Helicobacter pylori (H. pylori)* in adult human serum, plasma, or whole blood as an aid in the diagnosis of *H. pylori* infection in patients with clinical signs and symptoms of gastrointestinal disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. M. Poole acting for W.R. DuBois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991697

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

(Optional Format 1-2-96)