NOV 0 8 2001

K011709

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 K 011709.

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

Submitter: Trinity Biotech, plc
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Summary Date: May 30, 2001

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

Name (trade): Uni-Gold™ Strep A test kit

Name (usual): *Streptococcus* spp. serological reagents

Classification: 21 CFR 866.3740, Class 1, GTZ

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

The Uni-Gold™ Strep A test kit is substantially equivalent to the Quidel QuickVue® In-line™ One-Step Strep A Test (Quidel Corporation, 10165 McKellar Court, San Diego, CA 92121). The Uni-Gold™ Strep A test kit is identical, or similar to, its predicate device in terms of : antigen detection, technology/methodology, testing matrix, result interpretation, and clinical performance.

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

The extracted sample flows through an absorbent pad containing anti-Strep A antibody conjugated to colloidal gold which binds group A Streptococcal antigen if present, forming an antigen-antibody complex. As this complex travels along the membrane, it becomes immobilised at the test region, which is impregnated with a rabbit polyclonal anti-Strep A antibody, resulting in the formation of a pink/red line. A pink/red line will also appear in the control region of the test indicating proper functioning of the test. In the absence of group A Streptococcal antigen, a pink/red line will only appear in the control line.

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

The Trinity Biotech Uni-Gold™ Strep A test kit is intended for the rapid, *in vitro* qualitative detection of group A Streptococcal antigen from human throat swabs. It can also be used as a confirmation test of beta-haemolytic colonies obtained from blood agar plates. The test is intended for professional use in physicians offices as an aid in the rapid diagnosis of group A Streptococcal pharyngitis. The test may also be used in hospital laboratories as an aid in the rapid diagnosis of group A Streptococcal pharyngitis and the confirmation of group A *Streptococcus* from culture.

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

A summary of the similarities and differences between the Uni-Gold™ Strep A test kit and the predicate device follows.

Similarities Between Uni-Gold™ Strep A test kit and Predicate Device

Characteristics	Uni-Gold™ Strep A	Predicate device
Intended Use	Intended for the rapid, *in vitro* qualitative detection of group A Streptococcal antigen from human throat swabs. It can also be used as a confirmation of beta-haemolytic colonies obtained from blood agar plates. The test is intended for professional use in physicians' offices and hospital laboratories as an aid in the diagnosis and confirmation of group A Streptococcal pharyngitis.	Allows for the rapid detection of group A streptococcal antigen directly from patient throat swab specimens. The test is intended for use as an aid in the diagnosis of group A Streptococcal infection.
Methodology	Immunoassay	Immunoassay
Antigen Detected	Group A Strep	Group A Strep
Type of Test	Qualitative	Qualitative
Principle of the Test	The extracted sample flows through an absorbent pad containing anti-Strep A antibody conjugated to colloidal gold which binds group A Streptococcal antigen if present, forming an antigen-antibody complex. As this complex travels along the membrane, it becomes immobilised at the test region, which is impregnated with a rabbit polyclonal anti-Strep A antibody, resulting in the formation of a pink/red line. A pink/red line will also appear in the control region of the test indicating proper functioning of the test. In the absence of group A Streptococcal antigen, a pink/red line will only appear in the control line.	The extracted sample migrates through a label pad consisting of a pink label containing rabbit polyclonal anti-Strep A antibody and a blue control label. If the extracted solution contains Strep A antigen, the antigen will bind to the antibody on the pink test label which, in turn, will bind a second rabbit polyclonal anti-Strep A antibody spotted on the membrane, resulting in the formation of a pink-to-purple Test line. A blue Control line will also appear next to the letter "C" on the test cassette indicating proper functioning of the test. If Strep A is not present or present at very low levels, only a blue Control line will be visible.

Similarities Between Uni-Gold™ Strep A test kit and Predicate Device (Continued)

Characteristics	Uni-Gold™ Strep A	Predicate device
Materials required but not supplied	Timer or Stopwatch Tongue depressor Gloves	Timer Tongue blade or spoon Gloves
Test Matrix/ Specimen type	Throat swab	Throat swab
Specimen Collection and Preparation	Use only swabs provided. Collect throat swab specimens using standard throat swab collection methods. Depress the tongue with a tongue depressor. Be careful not to touch the teeth, tongue, sides or top of the mouth with the swab. Rub a sterile swab on the posterior pharynx, tonsils and inflamed areas. Process specimen samples as soon as possible after collection. Swabs can be held in a clean, dry paper sleeve at 15-30°C for up to 4 hours or at 2-8°C for up to 24 hours before processing.	Use only swabs provided. Collect throat swab specimens by standard clinical methods. Depress the tongue with a tongue blade or spoon. Be careful not to touch the tongue, sides or top of the mouth with the swab. Rub the swab on the back of the throat, on the tonsils, and in any other area where there is redness, inflammation or pus. Process specimen samples as soon as possible after collection. Swabs can be held in any clean, dry plastic tube or sleeve at 15-30°C for up to 4 hours or 24 hours refrigerated (2-8°C) before processing.
Controls provided	1 Positive control vial and 1 Negative control vial	1 Positive control swab and 1 Negative control swab
Extraction Buffers	2	2
Assay Read Time	5 minutes	5 minutes
Result Interpretation	Positive or Negative for Strep A antigen	Positive or Negative for Strep A antigen
Stability of Results	Results should be read after 5 minutes	Results should be read after 5 minutes
CLIA Waived	To be requested	Yes

Differences Between Uni-Gold™ Strep A test kit and Predicate Device

Characteristics	Uni-Gold™ Strep A	Predicate device
Re Use of Kit Controls	Yes. Controls are supplied enough for multiple tests	No. Only 1 positive and 1 negative control swab supplied each for single use only
Extraction Time	3 minutes	none
Storage Temperature	2-27°C (entire kit)	15-30°C (entire kit)

Brief Discussion of Nonclinical Data (21 CFR 807.92 (b) (1))
Laboratory studies were conducted to evaluate analytical sensitivity (lowest limit of detection) and analytical specificity (cross-reactivity testing from potential interferents). Summary description and results from those studies are provided below.

Analytical Sensitivity
Serial dilutions were prepared from two cultures of group A *Streptococcus*, and were tested with the Uni-Gold™ Strep A test kit until the interpretations became "negative".

The results indicate that the lowest level of detection of the Uni-Gold™ Strep A test kit is 1×10^5 cells per swab.

Analytical Specificity
The Uni-Gold™ Strep A test kit was used to test a variety of organisms at concentrations of approximately 1×10^7 cells per swab. Negative results were obtained in all cases.

Brief Discussion of Clinical Data (21 CFR 807.92 (b) (2))
Accuracy
The accuracy of the Trinity Biotech Uni-Gold™ Strep A test kit was determined through the analysis of 501 fresh throat samples tested both in the immunoassay and by routine culture.
The results from comparative testing between Uni-Gold™ vs. routine culture are presented below.

Uni-Gold™ Strep A Test Kit Results vs. Routine Culture Results

n = 501 samples		Routine	Culture
		+	-
Uni-Gold™ Strep A	+	97	3
	-	12	389
Reference Totals		109	392

The data indicated the Uni-Gold™ Strep A test kit correctly identified 97 of 109 positive results for a sensitivity of 89.0% and correctly identified 389 of 392 negative results for a specificity of 99.2%. The overall agreement between Uni-Gold™ Strep A test kit and routine culture was 97.0% (486/501). These data demonstrate good agreement between the two methods.

Uni-Gold™ Strep A vs predicate device

The results from the direct comparison of the two immunoassays are presented below.

Concordance results between Uni-Gold™ Strep A and Predicate device

	Uni-Gold™	Predicate device	Number	Percent of Total
Concordant Results	+	+	86	
	-	-	398	
				96.6%
Discordant Results	+	-	14	
	-	+	3	
				3.4%
Total Specimens Tested			501	100%

Good agreement was observed between the Uni-Gold™ Strep A test kit and predicate device. There was positive concordance in 96.6% of samples (86/89), and negative concordance in 96.6% of samples (398/412). Overall concordance was seen in 96.6% of the samples (484/501).

Culture Confirmation

The Uni-Gold ™ Strep A test kit was used to confirm the identification of group A Strep on blood agar plates. Samples that were visually positive on the culture assay were tested on the Uni-Gold ™ Strep A test kit and a Streptococcal latex grouping test kit as the predicate to confirm a positive result.

The Uni-Gold ™ Strep A test kit correctly identified 105/109 samples as group A *Streptococcus* giving a sensitivity of 96.3%. 2 of the 4 samples positive for Strep A on culture but negative by the Uni-Gold ™ Strep A test kit were identified by the Streptococcal latex grouping test as mixed cultures containing group A *Streptococcus*. The 2 further samples positive by culture and negative by the Uni-Gold ™ Strep A test kit were identified as non group A *Streptococcus (*group B *Streptococcus* and a mixed culture of group B and group F *Streptococcus*) . Thus, the Uni-Gold ™ Strep A test kit

correctly identified 105/107 samples as group A *Streptococcus* giving a sensitivity of 98.1% as compared against a Streptococcal latex grouping test.

In a further study of 224 samples, 117 of these were identified as non- Strep A colonies by morphology and the absence of beta-haemolysis. These were tested on the Uni-Gold ™ Strep A test where all negative samples were correctly identified. The results are summarized in the table below.

Culture Confirmation Study

n = 224 samples		Strep A Culture (confirmed by Beta-haemolysis and morphology)	
		+	-
Uni-Gold™ Strep A	+	105	0
	-	2	117
Reference Totals		107	117

In a separate study, colonies of 2 group A beta-haemolytic organisms and 4 non group A beta-haemolytic organisms were tested in duplicate in a blinded manner by 2 independent physicians. Correct results were obtained in all cases.

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

Analytical sensitivity of the Uni-Gold™ Strep A test kit was determined to be 1 x 10^5 cells per swab as demonstrated by the testing of serial dilutions in the assay. Analytical specificity testing demonstrated no interference by other organisms (pathological and nonpathological) routinely found in the throat.

The Uni-Gold™ Strep A test kit and the predicate device, with discordant results resolved against culture, revealed a relative sensitivity of Uni-Gold™ Strep A test kit of 99.0% (97/98 positive results) and a relative specificity of 99.3% (400/403 negative results). The relative overall agreement was 99.2% (497/501).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 0 8 2001

Ms. Fiona Campbell
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Re: K011709
Trade/Device Name: Trinity Biotech Uni-Gold™ Strep A Test Kit
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus spp. Serological Reagents
Regulatory Class: I
Product Code: GTY
Dated: August 17, 2001
Received: August 22, 2001

Dear Ms. Campbell:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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

NOV 0 8 2001

510(k) Number (if known): K011709 .

Device Name: **Trinity Biotech Uni-Gold™ Strep A test kit** .

Indications for Use:

The Trinity Biotech Uni-Gold™ Strep A test kit is intended for the rapid, *in vitro* qualitative detection of group A Streptococcal antigen from human throat swabs. It can also be used as a confirmation test of beta-haemolytic colonies obtained from blood agar plates. The test is intended for professional use in physicians offices as an aid in the rapid diagnosis of group A Streptococcal pharyngitis. The test may also be used in hospital laboratories as an aid in the rapid diagnosis of group A Streptococcal pharyngitis and the confirmation of group A *Streptococcus* from culture.

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription use ✓ Or Over the counter Use ____

(per 21 CFR 801.109)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011709/S1