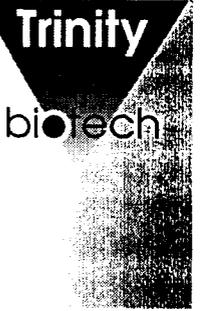


2/11/99

K982373



**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: K982373.

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

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

Contact: Dr. Jim Walsh  
Chief Operating Officer  
Trinity Biotech, plc  
phone: 011 353 1 276 9800  
fax: 011 353 1 276 9888

Summary Date: November 19, 1998

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 I, 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 TestPack® +Plus Strep A, (TestPack), Abbott Laboratories Inc., Chicago, IL. The Uni-Gold™ Strep A Test Kit is identical, or similar to, its predicate in terms of: intended use, antigen detected, technology/methodology, testing matrix, result interpretation, and clinical performance.

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

Immunoassay: Strep A antigen, when present, binds to the anti-Strep A antibody conjugated to a gold dye. As this complex travels along the membrane, it becomes immobilized at the test region, resulting in the formation of a red line. Excess antibody-gold conjugate further migrates along the membrane and binds to the control region, forming another red line. In the absence of Strep A antigen, a red line will only be formed at the control region.

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

The Trinity Biotech Uni-Gold™ Strep A Test Kit is a rapid immunoassay for the qualitative detection of Streptococcal A antigen from throat swabs, or the confirmation of beta-hemolytic colonies obtained from blood agar plates.

The Trinity Biotech Uni-Gold™ Strep A Test Kit is intended for use in hospital laboratories and physicians' offices as an aid in the diagnosis of Group A Streptococcal pharyngitis.

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

A summary table of the similarities and differences between the Uni-Gold™ Strep A Test Kit and the predicate device (TestPack + Plus Strep A) follows.

**Similarities Between Uni-Gold™ Strep A Test Kit and TestPack +Plus Strep A**

<b>CHARACTERISTIC</b>	<b>UNI-GOLD™ Strep A</b>	<b>TESTPACK® +PLUS Strep A</b>
<b>Intended Use</b>	qualitative detection of Group A <i>Streptococcal</i> antigen from throat swabs, or Group A confirmation from culture plates	qualitative detection of Group A <i>Streptococcal</i> antigen from throat swab specimens or confirmation of presumptive Group A <i>Streptococcal</i> colonies recovered from culture
<b>Antigen Detected</b>	Group A Strep	Group A Strep
<b>Methodology/Technology</b>	Immunoassay: Strep A antigen, when present, binds to the anti-Strep A antibody conjugated to a gold dye. As this complex travels along the membrane, it becomes immobilized at the test region, resulting in the formation of a red line. Excess antibody-gold conjugate further migrates along the membrane and binds to the control region, forming another red line. In the absence of Strep A antigen, a red line will only be formed at the control region.	Immunoassay: A positive sample proceeds through the membrane, and immobilizes the anti-Strep A antibody coated colloid. The sample and antibody-colloid complex migrate through the membrane to the Group A capture region, and then onto the end of the membrane. When the end of the assay window turns red, the result can be interpreted. If a red plus sign appears in the window, it indicates the presence of Group A antigen. The absence of the antigen will result in a minus sign.
<b>Testing Matrix</b>	throat swab or culture confirmation	throat swab or culture confirmation
<b>Result Interpretation</b>	positive or negative for Strep A antigen	positive or negative for Strep A antigen
<b>Assay Read Time</b>	5 minutes	5 minutes
<b>Conjugate Label</b>	Colloidal Gold	Colloidal Gold
<b>Extraction Time</b>	3 minutes	3 minutes
<b>Extraction Buffers</b>	2	2
<b>Testing Environment</b>	professional use	professional use

**Differences Between Uni-Gold™ Strep A Test Kit and TestPack +Plus Strep A**

<b>CHARACTERISTIC</b>	<b>UNI-GOLD™ Strep A</b>	<b>TESTPACK® +PLUS Strep A</b>
<b>Stability of Results</b>	should be read after 5 minutes, not more than 10 minutes	should be read after 5 minutes
<b>Neutralizing buffer</b>	none	one
<b>Storage Temperature</b>	2-27° C (entire kit)	2-8° C devices, 2-27° C buffers

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 colonies of Strep A cultures, and were tested with the Uni-Gold™ Strep A test Kit until the interpretations became “negative.” The assay demonstrated a sensitivity of  $1.0 \times 10^5$  cells/swab.

**Analytical Specificity**

The Uni-Gold™ Strep A Test Kit was used to test the following organisms at concentrations of approximately  $1 \times 10^8$ . Negative results were obtained in all cases.

NOTE: *Staphylococcus aureus* was tested at  $1 \times 10^6$  organisms.

<i>Bordetella pertussis</i>	<i>Staphylococcus aureus</i>
<i>Branhamella catarrhalis</i>	<i>Staphylococcus epidermidis</i>
<i>Candida albicans</i>	<i>Streptococcus mutans</i>
<i>Corynebacterium diphtheria</i>	<i>Streptococcus pneumoniae</i>
<i>Escherichia coli</i>	<i>Streptococcus pyogenes, Lancefield group B</i>
<i>Hemophilus influenzae</i>	<i>Streptococcus pyogenes, Lancefield group C</i>
<i>Klebsiella pneumoniae</i>	<i>Streptococcus pyogenes, Lancefield group D</i>
<i>Neisseria gonorrhoeae</i>	<i>Streptococcus pyogenes, Lancefield group F</i>
<i>Neisseria meningitidis</i>	<i>Streptococcus pyogenes, Lancefield group G</i>
<i>Neisseria sicca</i>	<i>Streptococcus sanguis</i>
<i>Pseudomonas aeruginosa</i>	



FEB 11 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Trinity Biotech, PLC  
c/o Erika B. Ammirati  
Ammirati Regulatory Consulting  
575 Shirlynn Court  
Los Altos, CA 94022

Re: K982373  
Trade Name: Uni-Gold™ Strep A Test Kit  
Regulatory Class: I  
Product Code: GTY  
Dated: January 4, 1999  
Received: January 12, 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.

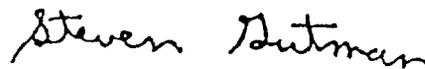
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

Page \_\_\_ of \_\_\_

510(k) Number (if known): K982373

Device Name: Uni-Gold™ Step A Test kit

Indications For Use:

The Trinity Biotech Uni-Gold Step A test kit is a rapid immunoassay for the qualitative detection of Streptococcal A antigen from throat swabs or the confirmation of beta-hemolytic colonies obtained from blood agar plates.

It is intended for use in hospital laboratories and physicians offices as an aid in the diagnosis of Group A Streptococcal pharyngitis.

(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 K982373

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)