FEB 1 0 2003

7. Summary of Safety and Effectiveness

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 K023766.

Submitter:
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121
Phone: 858-535-2030
Fax: 858-535-2035

Date:
October 31, 2002

Contact Person:
Edward Tung, Ph.D.

Product Name:
ACON® *Strep A Twist* Rapid Test Device

Common Name:
Immunochromatographic test for the qualitative detection of Group A Streptococcal antigen from a throat swab specimen.

Device Classification:
The ACON *Strep A Twist* Rapid Test Device is similar to other FDA-cleared devices for the qualitative detection of Group A Streptococcus Antigen from throat swab specimens. These tests are used to aid in the diagnosis of Group A Streptococcus infection. (21 CFR 866.3740). Serological test systems for the detection of Group A Streptococcus antigen have been classified as Class I devices.

Classification Name:
Streptococcus spp. Serological reagents

Intended Use:
The ACON *Strep A Twist* Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

Description:
The ACON® *Strep A Twist* Rapid Test Device is a qualitative, lateral flow immunochromatographic assay for the detection of Strep A antigen from a throat swab. The test is a heterogeneous, sandwich immunoassay, based on the principle of antigen-antibody immunochemistry, which uses a mixture of polyclonal antibodies to reliably produce a visually discernible colored line in the test region if Strep A antigen is present at a concentration of roughly 2.5 x 10^5 organisms per swab or greater.

Predicate Device:
Quidel QuickVue In-Line One-Step Strep A 510(k) Number K954257

Quidel Corp.
10165 McKellar Court
San Diego, California 92121

Comparison to a Predicate Device:
A summary comparison of the features of the ACON *Strep A Twist* Rapid Test Device and the Quidel QuickVue In-Line One-Step Strep A is shown below.

Feature		ACON® *Strep A Twist* Rapid Test Device		QuickVue In-Line One-Step Strep A
Intended Use		A rapid chromatographic immunoassay for the qualitative detection of Strep antigens from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.		The QuickVue In-Line One-Step Strep A allows for the rapid detection of group A streptococcal antigen directly from patient throat swabs. The test is intended to use as an aid in the diagnosis of group A streptococcal infection.
Indications for Use		Professional & point of care use.		Professional & point of care use.
Intended Specimen		Throat Swab		Throat Swab
Endpoint		Colored Lines		Colored Lines
Materials Provided		Test Devices Sterile Swabs Extraction Reagents A & B Positive Control (Non-viable Strep A) Negative Control (Non-viable Strep C) Package Insert Procedure Card		Test Cassettes Sterile Swabs Extraction Solution bottle Positive Control (Heat-inactivated Strep A) Negative Control (Heat-inactivated Strep C) Package Insert Procedure Card Extraction kit for use with Proficiency Testing samples only
Methodology		Membrane Particle Assay		Membrane Particle Assay
Extraction Reagent Color Reaction		Reagent A – Red Color Reagent B – Clear Color Combined Reagents – Yellow color		Reagent inside bottle – Clear Color Reagent inside ampoule – Clear Color Combined Reagents – Green color
Extraction Time		1 minute		up to 1 minute
Test Time		5 minutes		5 minutes
Format		Immunochemical, Strep A antigen /antibody, immunoassay principle		Immunochemical, Strep A antigen/antibody, immunoassay principle
Organism detection		Strep A specific		Strep A specific

Safety and Effectiveness Data:

Accuracy

A multi-center clinical evaluation was conducted with specimens from 758 patients presenting with signs and symptoms of pharyngitis. This evaluation compared the result of the ACON® *Strep A Twist* Rapid Test Device and another commercially available Strep A test device, the Quidel QuickVue In-Line One-Step Strep A test to the customary Strep A confirmed culture technique.

In this study, there were a total of four invalid results, two with the Quidel product and two with the ACON product. These invalid results were excluded from the data analysis. The data from this study yielded the following results:

ACON *Strep A Twist* Rapid Test Device compared to Quidel QuickVue In-Line One-Step Strep A.

Positive Agreement:	130/138 = 94% (89-97)*
Negative Agreement:	375/375 = 100% (99-100)*
Overall Agreement:	505/513 = 98% (97-99)*

ACON *Strep A Twist* Rapid Test Device compared to Strep A confirmed Culture

Sensitivity:	240/265 = 90% (86-94)*
Specificity:	464/491 = 94% (92-96)*
Accuracy:	704/756 = 93% (91-95)*

* Denotes 95% confidence intervals

Sensitivity

Nine (9) different strains of Strep A were evaluated with the ACON *Strep A Twist* Rapid Test Device. The minimum detectable level differed slightly depending upon the strain being tested. The detection level of all of the strains was roughly within one magnitude in concentration of each other. Seven (7) strains showed a minimum detectable level at roughly 10^4 organisms per swab while two (2) strains showed a minimum detectable level at roughly 10^5 organisms per swab.

In addition, the throat swab specimens from the study that yielded beta-hemolytic colony growth were assigned a semi-quantitative value expressed as rare, 1+, 2+, 3+ or 4+. The ability of the ACON *Strep A Twist* Rapid Test Device to detect these various concentration levels is shown below.

Culture Classification	ACON/Culture	% Correct
Negative (Specificity)	464/491	94%
Rare	4/11	36%
1+	16/20	80%
2+	17/23	74%
3+	26/29	90%
4+	175/182	96%
Total Positive (Sensitivity)	238/265	90%
Total (Overall Agreement)	702/756	93%

Specificity

Specificity studies were conducted by individually spiking the various bacterial strains listed below on swabs at a final concentration of 1.0×10^7 org/swab, then evaluating the swabs in duplicate according to the package insert. None of the organism demonstrated any cross-reactivity in the test. The organisms tested were:

Bordetella pertussis
Branhamella catarrhalis
Candida albicans
Corynebacterium diphtheriae
Enterococcus durans
Enterococcus faecalis
Hemophilus influenzae
Klebsiella pneumoniae
Neisseria gonorrhea
Neisseria meningitidis
Neisseria sicca
Neisseria subflava
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Staphylococcus epidermidis
Strep B
Strep C
Strep F
Strep G
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus sanguis
Streptococcus intermedius
Streptococcus oralis
Streptococcus mitis
Streptococcus anginosus
Escherichia coli

Interfering Substances

No interference to an expected negative or positive result was observed in our studies when using specimens containing the following substances at a final concentration of 1% (Mucin at 1 mg/swab):

Cherry Halls Cough Drops
Menthol Halls Cough Drops
Robitussin Cough Syrup
Dimetapp Cough Elixir
Whole Blood at 100uL
Vicks Chloraseptic Spray
Cepacol Sore Throat Spray
Listerine Mouthwash
Scope Mouthwash
Mucin (at 1 mg/swab)

Intra and Inter-assay Variability
Studies to evaluate inter- and inter-assay variability demonstrated that the test yielded that expected results >99% of the time

Lot-to-Lot Variability
Studies to evaluate the manufacturability and consistency of the product on a lot-to-lot basis have shown this test to be highly reproducible.

Conclusion
These studies demonstrate the substantial equivalency of the ACON® *Strep A Twist* Rapid Test Device to the Quidel QuickVue In-Line One-Step Strep A, which is already marketed. They further demonstrate the suitability of this product for professional and point-of-care use, in addition to demonstrating its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 0 2003

Edward Tung, Ph.D.
Director of Regulatory Affairs
Acon Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, CA 92121

Re: k023766
Trade/Device Name: Acon® Strep A Twist Rapid Test Device
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus Spp. Serological Reagents
Regulatory Class: Class I
Product Code: GTY
Dated: November 8, 2002
Received: November 12, 2002

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

9. INDICATIONS FOR USE

510(k) Number: K023766

Device Name: The ACON® Strep A Twist Rapid Test Device

Indications For Use: The ACON® *Strep A Twist* Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection. This test is indicated for professional and point of care use only.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use_____

(Per 21 CFR 801.109)

Freddie Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K023766