AUG - 4 2003

SUMMARY OF 510(k)

This summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is **K031759**.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

July 28, 2003

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON Spectrum Multi-Drug Multi-Line Screen Test Card

ACON Spectrum Multi-Drug Multi-Line Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup)

Common Name:

Immunochromatographic test for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine.

Device Classification:

Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine test systems have been classified as Class II devices with moderate complexity.

The ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine.

Intended Use:

The ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with three types of Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup, and ACON 009 Cup or E-Z Split Key Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine.

These assay systems can only provide a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, especially when preliminary positive results are indicated.

They are only intended for healthcare professionals including professionals at point of care sites.

Description:

The ACON Spectrum Multi-Drug Multi-Line Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine at the cutoff concentrations of:

50 ng/mL for Marijuana,
300 ng/mL for Cocaine,
1,000 ng/mL for Methamphetamine,
1,000 ng/mL for Amphetamine,
2,000 or 300 ng/mL for Opiates (OPI2000 or MOP300),
25 ng/mL for Phencyclidine,
300 ng/mL for Benzodiazepine,
300 ng/mL for Methadone,
300 ng/mL for Barbiturate,
1,000 ng/mL for Tricyclic Antidepressants,
and 500 ng/mL for Methylenedioxymethamphetamine.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine at the concentrations below the designated cut-off levels will generate a colored-line in the designated test region for the drug. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified ACON Devices

The ACON® Spectrum Multi-drug Multi-line Drug Screen Test Card (12-in-4) is a "combined" product format of the two previously cleared 6-in-2 ACON One Step Multi-drug Multi-line Drug Test Card. The test Cards in these 6-in-2 formats have up to six DOA tests on one or two Test Strips. These two legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

Table 1. Unmodified ACON Devices with K Numbers and Product Codes.

ACON DOA Test		K Number	Product Code
1. ACON One Step Multi-drug Multi-line Test Card & Test Device with drug calibrator and cutoff concentration used for each analyte listed		**K020313**	
COCAINE ((Benzoylecgonine)	300 ng/mL		DIO
AMPHETAMINE (Amphetamine)	1,000 ng/mL		DKZ
OPIATES (Morphine)	2,000 ng/mL		DJG
METHAMPHETAMINE (Methamphetamine)	1,000 ng/mL		LAF
MARIJUANA (Δ-11-nor-9-THC-9-COOH)	50 ng/mL		LDJ
Phencyclidine (PCP)	25 ng/mL		LCM
2. ACON One Step Multi-drug Multi-line Test Card & Test Device (II) with drug calibrator and cutoff concentration used for each analyte listed		**K023946**	
TRICYCLIC ANTIDEPRESSANTS (Nortriptyline)	1,000 ng/mL		DJC
MDMA (Methylenedioxymethamphetamine)	500 ng/mL		LFG
BENZODIAZEPINE (Oxazepam)	300 ng/mL		JXM
METHADONE (Methadone)	300 ng/mL		DJR
BARBITURATES (Secobarbital)	300 ng/mL		DIS
MORPHINE (Morphine)	300 ng/mL		DJG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 4 2003

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

Re: k031759
Trade/Device Name: ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup)
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ; DIO; DJC; DKZ; DJG; LCM; JXM; DJR; DIS; LFG
Dated: July 7, 2003
Received: July 11, 2003

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). You may obtain other general information on your responsibilities under the Act 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

INDICATION FOR USE:

510(k) Number: K031759

Device Name: ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup)

Indications for Use: The ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with three types of Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine at the cutoff concentrations of:

50 ng/mL for Marijuana,
300 ng/mL for Cocaine,
1,000 ng/mL for Methamphetamine,
1,000 ng/mL for Amphetamine,
2,000 or 300 ng/mL for Opiates (OPI2000 or MOP300),
25 ng/mL for Phencyclidine,
300 ng/mL for Benzodiazepine,
300 ng/mL for Methadone,
300 ng/mL for Barbiturate,
1,000 ng/mL for Tricyclic Antidepressants, and
500 ng/mL for Methylenedioxymethamphetamine

These assay systems can only provide a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, especially when preliminary positive results are indicated.

They are only intended for healthcare professionals including professionals at point of care sites.

(Please do not write below this point)

Concurrence of CDRH, Office of *In Vitro* Device Evaluation and Safety

Prescription Use ✓ Or over-the-counter Use _____

(Per 21 CFR 801.109)

Division Sign-Off For Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

K031759