Summary of Safety and Effectiveness

The sponsor, Syntron Bioresearch, Inc. (2774 Loker Ave. West, Carlsbad, California, 92008), has developed, manufactured, and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Phencyclidine (PCP) and its metabolites in a screening format.

The trade name of the device is QuikStrip One Step Phencyclidine (PCP) Test having a designated common name of Phencyclidine (PCP) Test System and a classification as a Class II device per FDA. This device is intended for the medical/forensic screening of urine.

Syntron's QuikStrip One Step Phencyclidine (PCP) Test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody:antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 25 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

In-house testing of Syntron's QuikStrip One Step Phencyclidine (PCP) Test yielded a relative sensitivity or agreement within positive samples of 1.000 and relative specificity or agreement within negative samples of 1.000 and an accuracy of 100% when tested against Syva EMIT® (25) II on samples documented to be positive by GC/MS. A clinical trial consisting of 286 samples was run and the combined data yielded a relative sensitivity of 100%, a relative specificity of 100% with an accuracy of 100% when compared to Emit II® run at 25 ng/ml. By non parametric testing the results are not significantly different from one another. Both Emit II and QuikStrip yielded 2 false positives due to the presence of Phencyclidine (PCP) at levels below 25 ng/ml, but above 20 ng/ml as determined by GC/MS.

All positive samples by either screening method were confirmed by GC/MS (25 ng/ml) . The testing performed by the Clinical Trial site did find 2 false positives and no false negatives in the samples tested. The False Positives were due to the presence phencyclidine (PCP) between 20 and 25 ng/ml by GC/MS.

Additional information on this submission may be obtained by contacting Dr. Cleve W. Laird, President, Drial Consultants, Inc. at 805-522-6223(Ca) or by fax at 805-522-1526.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 7 1998

Syntron Bioresearch, Inc.
C/O Drial Consultants, Inc.
Cleve W. Laird, Ph.D.
1420 Los Angeles Avenue, Suite 201
Simi Valley, California 93065

Re: K981019
QuickStrip One Step Phencyclidine (PCP) Test
Regulatory Class: II
Product Code: LCM, EIA
Dated: March 17, 1998
Received: March 18, 1998

Dear Dr. Laird:

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 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 (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): To Be Assigned

Device Name: QuikStrip One Step Phencyclidine (PCP) Test

Indications For Use:

INTENDED USE

Syntron's QuikStrip One Step Phencyclidine (PCP) assay is a rapid, qualitative, competitive binding immunoassay for the determination of Phencyclidine (PCP) in urine at the cutoff level of 25 ng/ml. The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrophotometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated[6]. Syntron's QuikStrip One Step Phencyclidine (PCP) Test is not intended to monitor drug levels, but only to screen urines for the presence of Phencyclidine (PCP) and its metabolites.

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

Concurance of CDRH, Office of Device Evaluation (ODE)

Carol Benson for Alfred Montgomery

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981019

Perscription Use: ✓ **or** **Over The Counter Use:** _____
(Per 21 CFR 801.109 **(Optional Format 1-2-96)**