15.1 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 Strip Holder that will accommodate 2 to 8 of the company's cleared drugs of abuse strips for the qualitative detection in urine of drugs of abuse and their metabolites in a quick, simple, easy to read, screening format.

The trade name of the device is DrugCheck X Multidrug Screening Device (X is replaced by 2, 3, 4, 5, 6, 7, or 8) having a designated common name of Strip Holder and a classification as a Class II device per FDA. This device is intended for the medical/forensic screening of urine for drugs of abuse.

Syntron's DrugCheck X Multidrug Screening Device (X is replaced by 2, 3, 4, 5, 6, 7, or 8) consists of two to eight (2-8) individual chromatographic absorbent devices 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 for each drug. 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, different for each drug, 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 specified by SAMHSA for GC/MS. 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. Each of the test strips in the holder functions independently and is read independently.

In-house testing of DrugCheck X Multidrug Screening Device yielded no observations of inappropriate reactions or interference between tests on samples designed to test for interference and inappropriate reactions. A clinical trial consisting of 565 clinical samples was run and the results revealed no inappropriate reactions or interference. The observations were not significantly different from those obtained by either Emit II or GC/MS. When tested by non parametric statistical methods the results are not significantly different from one another. All positive samples by either screening method were confirmed 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP -2 1999

Syntron Bioresearch, Inc.
c/o Mr. James M. Barquest
California Department of Health
Food and Drug Branch
601 North Seventh Street (MS-357)
P.O. Box 942732
Sacramento, California 94234

Re: K992748
Trade Name: QuikStrip DrugCheck X Multidrug Screening Device
Regulatory Class: II
Product Code: DIO, LDJ, DKZ, DPK, LCM
Dated: August 9, 1999
Received: August 16, 1999

Dear Mr. Barquest:

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

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/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

510(k) Number (if Known): Not Yet Assigned

Device Name: DrugCheck X Multidrug Screening Device

Indications For Use:

Syntron's DrugCheck X Multidrug Screening Device (the X may be replaced by 2, 3, 4, 5, 6, 7, or 8) is a holder for up to eight rapid, qualitative, competitive binding immunoassay strips for the detection of drugs of abuse in urine at the SAMHSA designated GC/MS cutoff levels. The test strips available for inclusion in the DrugCheck X are Amphetamine, Methamphetamine, Benzodiazepine, Barbiturates, Cocaine, Marijuana (THC), Opiates, and Phencyclidine (PCP).**The tests provide 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 DrugCheck X Multidrug Screening Device is not intended to monitor drug levels, but only to screen urines for the presence of specific drugs of abuse and their metabolites.**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K977748

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

FOOD & DRUG BRANCH
JUN 18 1999