Summary of Safety and Effectiveness

The sponsor, Bionike Laboratories, Inc. (1015 Grandview, South San Francisco, CA 94080-4910) has developed, manufactured and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Barbiturate and its metabolites in a screening format.

The trade name of the device is Bionike AQ™ Barbiturate Test having a designated common name of Barbiturate Test System and a classification as a Class II device per 21 CFR ¶ 862.3150. This device is intended for the medical/forensic screening of urine.

Bionike Laboratories' AQ™ Barbiturate 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 cutoff level of 200 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 Bionike Laboratories' AQ™ Barbiturate Test yielded a relative sensitivity or agreement within positives and relative specificity or agreement within negatives of 1.00 and an accuracy of 100% when tested against Syva EMIT® II on samples documented to be positive by GC/MS. A clinical trial consisting of 296 samples was run and the combined data yielded a relative sensitivity or agreement within positives of 97.96%, a relative specificity or agreement within negatives of 100% with an accuracy of 98.99%.

All positive samples by either screening method were confirmed by GC/MS. Four of the 3 samples were negative for Barbiturate, but positive for other drugs by GC/MS. The three samples were positive for either Bromocriptine or Zoloft.

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

JUN 28 1999

Bionike, Inc.
c/o Dr. Cleve W. Laird
Drial Consultants, Inc.
1420 Los Angeles Avenue, Suite 201
Simi Valley, California 93065

Re: K990280
Trade Name: AQ™ Barbiturate Test
Regulatory Class: II
Product Code: DIS
Dated: May 18, 1999
Received: May 20, 1999

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 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.

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): To be Assigned

Device Name: AQ™ Barbiturate Test

Indications For Use:

Bionike Laboratories' AQ™ Barbiturate Test is a rapid, qualitative, competitive binding immunoassay for the determination of Barbiturates in urine at the cutoff level of 200 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]. Bionike Laboratories' AQ™ Barbiturate Test is not intended to monitor drug levels, but only to screen urines for the presence of Barbiturate and its metabolites.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990280

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