DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 4 2001

Mr. Raphael Wong
President,
Branan Medical Corporation
10015 Muirlands Road, Suite E
Irvine, CA 92618

Re: K012541
Trade/Device Name: Fastix™ Drug Screen THC/COC Dipstick Test, Fastix™ Drug Screen THC/COC/MET Dipstick Test, Fastix™ Drug Screen OPI/MET/THC/COC, Dipstick Test, and Fastix™ Drug Screen OPI/AMP/THC/COC Dipstick Test
Regulation Number: 21 CFR 862.3870, 862.3250, 862.3610, 862.3640, 862.3100
Regulatory Class: II
Product Code: LDJ, DIO, LAF, DKZ, DJG
Dated: August 1, 2001
Received: August 7, 2001

Dear Mr. Wong:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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" (21CFR 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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~K004034~~ K012541

Device Name: **Fastix™ Drug Screen THC/COC Dipstick Test**

Indications For Use:

The Branan Medical Corporation Fastix™ Drug Screen THC/COC Dipstick Test is an *in vitro* screen test for the rapid detection of THC (11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid) and Benzoylecgonine (cocaine metabolite) in human urine. The cutoff concentrations are as follows:

THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**

The test kit is used to obtain a visual, qualitative result and is intended for professional use only. It is not intended for over-the-counter sale to lay persons.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kevia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012541

510(k) Number (if known): ~~K004034~~ K012541

Device Name: **Fastix™ Drug Screen THC/COC/MET Dipstick Test**

Indications For Use:

The Branan Medical Corporation Fastix™ Drug Screen THC/COC/MET Dipstick Test is an *in vitro* screen test for the rapid detection of THC, Cocaine and Methamphetamine in human urine. The cutoff concentrations are as follows:

THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**
MET	**D-Methamphetamine**	**1000 ng/ml**

The test kit is used to obtain a visual, qualitative result and is intended for professional use only. It is not intended for over-the-counter sale to lay persons.

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(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kevin Alexander Jr/Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012541

510(k) Number (if known): ~~K004034~~ K012541

Device Name: **Fastix™ Drug Screen OPI/MET/THC/COC Dipstick Test**

Indications For Use:

The Branan Medical Corporation Fastix™ Drug Screen OPI/MET/THC/COC Dipstick Test is an *in vitro* screen test for the rapid detection of Opiate, Methamphetamine THC, and Cocaine in human urine. The cutoff concentrations are as follows:

OPI	**Morphine**	**2000 ng/ml**
MET	**D-Methamphetamine**	**1000 ng/ml**
THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**

The test kit is used to obtain a visual, qualitative result and is intended for professional use only. It is not intended for over-the-counter sale to lay persons.

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(Optional Format 1-2-96)

Kesia Alexander Jr Stan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012541

510(k) Number (if known): ~~K004034~~ K012541

Device Name: **Fastix™ Drug Screen OPI/AMP/THC/COC Dipstick Test**

Indications For Use:

The Branan Medical Corporation Fastix™ Drug Screen OPI/AMP/THC/COC Dipstick Test is an *in vitro* screen test for the rapid detection of Opiate, Amphetamine, THC and Cocaine in human urine. The cutoff concentrations are as follows:

OPI	**Morphine**	**2000 ng/ml**
AMP	**Amphetamine**	**1000 ng/ml**
THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**

The test kit is used to obtain a visual, qualitative result and is intended for professional use only. It is not intended for over-the-counter sale to lay persons.

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