DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 8 2001

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

Re: K004034
Trade Names: Monitect™ Multiple Drug Screen MOR2000/AMP Test
Monitect™ Multiple Drug Screen MOR2000/MET Test
Monitect™ Multiple Drug Screen THC/COC/PCP Test
Monitect™ Multiple Drug Screen MOR2000/AMP/THC/COC/PCP Test
Monitect™ Multiple Drug Screen MOR2000/MET/THC/COC/PCP Test
Regulatory Class: II
Product Code: DKZ, DIO, DJC, DOE, LDJ, DJG
Dated: December 27, 2000
Received: December 28, 2000

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 (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.

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

510(k) Number (if known): K004034

Device Name: **Monitect™ Multiple Drug Screen MOR2000/AMP Test**

Indications For Use:

The Branan Medical Corporation Monitect™ Multiple Drug Screen MOR2000/AMP Test is an *in vitro* screen test for the rapid detection of Morphine and Amphetamines in human urine. The cutoff of this test is set at the following concentrations:

MOR	**Morphine**	**2000 ng/ml**
AMP	**Amphetamines**	**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.

Dan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K004034

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

510(k) Number (if known): K004034

Device Name: **Monitect™ Multiple Drug Screen MOR2000/MET Test**

Indications For Use:

The Branan Medical Corporation Monitect™ Multiple Drug Screen MOR2000/MET Test is an *in vitro* screen test for the rapid detection of Morphine and Methamphetamine in human urine. The cutoff of this test is set at the following concentrations:

MOR	**Morphine**	**2000 ng/ml**
MET	**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.

Ian Coogan
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K004034

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

510(k) Number (if known): K004034

Device Name: **Monitect™ Multiple Drug Screen THC/COC/PCP Test**

Indications For Use:

The Branan Medical Corporation Monitect™ Multiple Drug Screen THC/COC/PCP Test is an *in vitro* screen test for the rapid detection of THC (11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid), Benzoylecgonine (cocaine metabolite) and Phencyclidine in human urine. The cutoff of this test is set at the following concentrations:

THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**
PCP	**Phencyclidine**	**25 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.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 004034

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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)

510(k) Number (if known): K004034

Device Name: **Monitect™ Multiple Drug Screen MOR2000/AMP/ THC/COC/PCP Test**

Indications For Use:

The Branan Medical Corporation Monitect™ Multiple Drug Screen MOR2000/AMP/ THC/COC/PCP Test is an *in vitro* screen test for the rapid detection of Morphine, Amphetamines, THC (11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylicacid), Benzoylecgonine (cocaine metabolite) and Phencyclidine in human urine. The cutoff of this test is set at the following concentrations:

MOR	**Morphine**	**2000 ng/ml**
AMP	**Amphetamines**	**1000 ng/ml**
THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**
PCP	**Phencyclidine**	**25 ng/ml**

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Dean Cooper
(Division Sign-Off)
Division
Work K004034

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

(Optional Format 1-2-96)

Page 1 of 1

510(k) Number (if known): K004034

Device Name: **Monitect™ Multiple Drug Screen MOR2000/MET/THC/COC/PCP Test**

Indications For Use:

The Branan Medical Corporation Monitect™ Multiple Drug Screen MOR2000/MET/THC/COC/PCP Test is an *in vitro* screen test for the rapid detection of Morphine, Methamphetamine, THC (11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylicacid), Benzoylecgonine (cocaine metabolite) and Phencyclidine in human urine. The cutoff of this test is set at the following concentrations:

MOR	**Morphine**	**2000 ng/ml**
MET	**Methamphetamine**	**1000 ng/ml**
THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
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