DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

NOV 0 7 2001

Re: k013124
Trade/Device Name: Scooper ™ Drug/Adulteration Test Cup-
MOR/AMP/THC/COC/PCP Drug Screen Tests with Adulteration Pads for Creatinine, Nitrite, pH and Oxidizing Agents
Regulation Number: 21 CFR 862.3650; 21 CFR 862.3100; 21 CFR 862.3870; 21 CFR 862.3250
Regulation Name: Opiate test system; Amphetamine test system; Cannabinoid test system; Cocaine and cocaine metabolite test system
Regulatory Class: Class II; Class II; Class II, Class II
Product Code: DJJ; DKZ; LDJ; DIO
Dated: October 18, 2001
Received: October 22, 2001

Dear Mr. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

K013124

NOV 0 7 2001

510(k) Number (if known): K013124

Device Name: **Scooper™ Drug/Adulteration Test Cup - MOR/AMP/THC/COC/PCP Drug Screen Tests with Adulteration Pads for Creatinine, Nitrite, pH and Oxidizing Agents**

Indications For Use:

The Scooper™ Drug/Adulterant Test Cup is an *in vitro* screen test for the rapid detection of morphine, amphetamines, THC, cocaine and phencyclidine in human urine. The cutoff concentrations are as follows:

OPI	**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**

The Scooper™ Drug/Adulteration Test Cup is used to obtain visual, qualitative results and is intended for professional use only. It is not intended for over-the-counter sale to lay persons.

Dean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013124

(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)