DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 18 1998

Jemo Kang, Ph.D., M.B.A.
Director
Princeton BioMeditech Corporation
P.O. Box 7139
Princeton, NJ 08543-7139

Re: K983501
Trade Name: AccuSign® DOA 10, AccuSign DOA Panel, AccuSign MET/OPI/ COC/THC/PCP/BZO/BAR/MTD/TCA/AMP
Regulatory Class: II
Product Code: LAG,DJG,DIO,DKE,LCM,DIS,DKN,DJR,LFI and DKZ
Dated: October 5, 1998
Received: October 6, 1998

Dear Dr. Kang:

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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

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): K983501

ice Name: AccuSign® DOA 10 (MET/OPI/COC/THC/PCP/ BZO/BAR/MTD/TCA/AMP)

Indications For Use:

Immunoassay for the qualitative detection of methamphetamine, opiates, cocaine metabolites, THC metabolites, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, methadone, and amphetamine in human urine to assist in screening of drug of abuse samples. The detecting cut-off concentrations are as follows:

MET	D-Methamphetamine	1000 ng/mL
OPI	Morphine	300 ng/mL
COC	Benzoylecgonine	300 ng/mL
THC	11-nor-Δ^9-9-carboxylic acid	50 ng/mL
PCP	Phencyclidine	25 ng/mL
Benzodiazepine	Oxazepam	300 ng/mL
Barbiturate	Secobarbital	300 ng/mL
Methadone	Methadone	300 ng/mL
TCA	Nortriptyline	1000 ng/mL

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number _____

Professional Use: X

Prescription Use: X OR Over The Counter Use: _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)