



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC - 3 1997

John F. Bruni, Ph.D.  
• Director, Clinical and Regulatory Affairs  
Biosite Diagnostics  
11030 Roselle Street  
San Diego, California 92121

Re: K973784  
Triage® Panel for Drugs of Abuse plus Tricyclic  
Antidepressants and Opiates 2000  
Regulatory Class: II  
Product Code: DKZ, DIS, JXM, DIO, DJR, DJG, LFG, LCM  
Dated: October 1, 1997  
Received: October 3, 1997

Dear Dr. Bruni:

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 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 (Pre-market 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 pre-market 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.

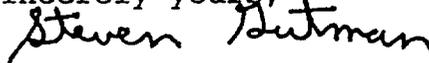
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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 12973784

- Device Names: Triage® Panel for Drugs of Abuse plus Tricyclic Antidepressants – Opiates 2000 – 8 test panel
- Triage® Panel for Drugs of Abuse– Opiates 2000 – 7 test Panel
- Triage® Panel for Drugs of Abuse plus Methadone – Opiates 2000 – Methadone substituted for PCP
- Triage® 8 Panel for Drugs of Abuse - Opiates 2000 – Methadone substituted for PCP
- Triage® Intervention Panel for Drugs of Abuse - Opiates 2000 – 5 test panel
- Triage® Panel for Drugs of Abuse plus Tricyclic Antidepressants –8 test panel
- Triage® Panel for Drugs of Abuse – 7 test Panel
- Triage® Panel for Drugs of Abuse plus Methadone - Methadone substituted for PCP
- Triage® 8 Panel for Drugs of Abuse - Methadone substituted for PCP
- Triage® Intervention Panel for Drugs of Abuse - 5 test panel

The above products have the screening cut-off concentrations s outlined below:

Indications for Use:

The Triage® Panel for Drugs of Abuse plus Tricyclic Antidepressants - Opiates 2000 (and other forms of the product )is an immunoassay used for the qualitative determination of the presence of the major metabolites of drugs of abuse, Phencyclidine, -Benzodiazepines, Cocaine Metabolite, Amphetamines, THC, Opiates, Barbiturates, and Tricyclic Antidepressants in urine.

The cut-off concentrations are provided below:

MTD	Methadone	300 ng/mL
PCP	Phencyclidine	25 ng/mL*
BZO	Benzodiazepines	300 ng/mL
COC	Cocaine (Benzoylcegonine)	300 ng/mL
AMP	Amphetamines	1000 ng/mL*
THC	THC(11-nor $\Delta^9$ -THC-9-carboxylic acid)	50 ng/mL*
OPI	Opiates (Morphine)	2000 ng/mL (300 ng/mL-other test formats)
BAR	Barbiturates	300 ng/mL
TCA	Tricyclic Antidepressants	1000 ng/mL

(Division Sign-Off)  
 Division of Clinical Laboratory Devices  
 510(k) Number 12973784

**This test provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional-judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

**The tricyclic test is a qualitative screening test. A negative result does not eliminate the possibility of the presence of tricyclic antidepressants in the urine specimen at concentrations lower than 1000 ng/mL. Should confirmation of the test result for the parent compound or the metabolites be desired, an alternative method that is capable of identification and quantification should be used, e.g. HPLC, GC or GC/MS. A positive screening result may be due to the sum of the reactivity of the parent tricyclic antidepressant and the various metabolites of the respective compound.**

\* Recommended Screening cut-off concentrations by the Substance Abuse and Mental Health Services Administration formerly the National Institute on Drug Abuse.

(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

(Optional Format 1-2-96)