



JAN 28 1998

K974762

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. It is submitted by Mary Freeman of Awareness Technology which is located at the address given below. The telephone and fax numbers are also given below.

BASIS FOR EQUIVALENCE: Stat Tracks is a dedicated software interface and reporting tool comparable to any other commercially available software. It is also comparable to manual writing, graphing, and filing.

USE OF THE DEVICE: Stat Tracks is to be used by the lab technician operating the analyzer so that computer entry and data storage can replace manual methods. This software is not used to measure, calculate, or qualify test results. The purpose of this program is to facilitate the lab worker's job, mainly by saving time and money. Instead of buying a pre-printed lab report form and typing in the results, for example, the lab can print a form from the computer with the results in it.

CRITICALITY: The program is not used with any device that comes in contact with patients, nor any life supporting equipment. It is used by laboratory professionals in the processing of diagnostic in vitro testing. The worst case scenario is that a correct laboratory result is printed for the wrong test or patient, somehow caused by the software, and that it is reported, and considered plausible by the treating physician, and leads to delayed or inappropriate treatment having adverse effects. Use of this software in place of another program or a manual method, does not increase the likelihood of such an event. Since the chemistry analyzer is a manual one, the user remains responsible for entering the specimens one-by-one in the correct order.

DESIGN ASSURANCE TESTING: Stat Tracks has been tested to verify that the design will produce intended results. Studies confirm activation of appropriate error messages as well. No device-induced case of mis-identification of a patient result has been found under any circumstance of testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 28 1998

Mary Freeman
President
Awareness Technology Inc.
P.O. Box 1679
1995 SW Martin Highway
Palm City, Florida 34991

Re: K974762
Stat Tracks
Regulatory Class: I
Product Code: JJQ
Dated: December 18, 1997
Received: December 19, 1997

Dear Ms. Freeman:

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 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.

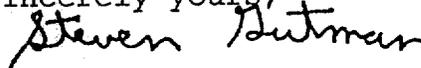
Page 2

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): K974762

Device Name: common name = PC program; proprietary name = Stat Tracks

Indications For Use:

This accessory program may be used by customers with the general purpose analyzer (K882938) who want to link their instrument to a PC for the purpose of transferring the data from the general purpose instrument to the PC, instead of having the data typed manually by a data entry person

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

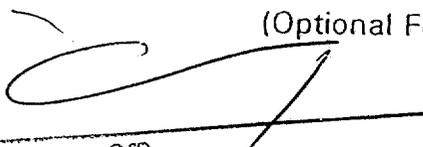
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K974762