

510(k) Summary

Landmark Scientific Inc.

Common/Classification Name: Centrifugal Chemistry Analyzer for Clinical Use
21 CFR 862.2140, Class I

Sponsor: Landmark Scientific Inc.
110-B Creek Ridge Road
Greensboro, NC 27406

Tel.: (910) 373-0274
FAX: (910) 373-1326

Contact: Steve Kincaid

Prepared: June 17, 1997

A. LEGALLY MARKETED PREDICATE DEVICES

The **AG^{II} Automated Chemistry Analyzer System** is substantially equivalent to its predicate device currently marketed by Landmark Scientific, the AutoMed Centrifugal Analyzer with Automated Rotor Loader (K781900 and K853453).

B. DEVICE DESCRIPTION

The **AG^{II} Automated Chemistry Analyzer** is the latest in a series of automated blood chemistry analyzers for the clinical chemistry laboratory that have become more and more compact as the miniaturization of the technology of the various components has proceeded. The **AG^{II}** weighs only 37% as much as the currently marketed device, the ASCA **Automated Spin Chemistry Analyzer**, and has a "footprint" only about one-third as large. The **AG^{II}** is controlled with a personal computer with a good color monitor, floppy disk drive, hard drive, and printer.

The cuvette rotor has a unique self-contained design. Forty cuvettes make up a single cuvette rotor. Each cuvette is made up of a sample shelf and reagent well. The design allows reactions to be completed in the rotor rather than having to be transferred upon mixing, by centrifugal force, to a separate cuvette or reading chamber. The pump uses a rack and pinion drive with a resolution of 3000 steps. The integrated pipettor/dilutor boasts an accuracy of \pm 1.0% at full stroke and a

precision of \pm 0.05% CV within-run at full stroke. This provides excellent accuracy and precision over a wide range of volumes and speeds.

C. INTENDED USE

The AG^{II} Chemistry Analyzer is indicated for in vitro diagnostic use for the quantitative determination of body fluid constituents using automated spectrophotometric methods.

D. TECHNOLOGICAL CHARACTERISTICS

The **AG^{II} System** has the same technological characteristics as the predicate device. The **AG^{II}** is simply a modification with updated hardware and cosmetic changes from the predicate device.

E. TESTING

Landmark Scientific carried out testing to address the following issues:

- (1) electrical safety;
- (2) electromagnetic compatibility;
- (3) precision;
- (4) accuracy of results for standard samples; and
- (5) comparison of performance of the AG^{II} and predicate device on clinical samples.

The results from these tests supported the safety and effectiveness of the AG^{II} System and demonstrated that it is substantially equivalent to the predicate device.

F. CONCLUSIONS

The **AG^{II}** device has the *same* intended use as the predicate device. Landmark Scientific Inc. has demonstrated through its performance tests on the **AG^{II} System** and its comparison of the **AG^{II}** characteristics with those of the predicate device that the **AG^{II} System** is substantially equivalent to the predicate device.



AUG 28 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

T. Whit Athey, Ph.D.
Senior Consultant
Landmark Scientific, Inc.
110-B Creek Ridge Road
Greensboro, North Carolina 27406

Re: K972409
Trade Name: AG^{II} Chemistry Analyzer System
Regulatory Class: I
Product Code: JJG
Dated: June 25, 1997
Received: June 26, 1997

Dear Dr. Athey:

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 (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 requirement, 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.

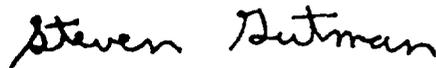
Page 2

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 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K972409

Device Name: AG^{II} Clinical Chemistry Analyzer

Indications For Use:

The AG^{II} Chemistry Analyzer is indicated for in vitro diagnostic use for the quantitative determination of body fluid constituents using automated spectrophotometric methods.

(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 K972409

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use