FEB 17 2006

K053253

10.0 510(k) Summary

Submitter: HemoCue AB
Box 1204
Angelholm, Sweden SE-262 23

+46 431 45 82 00 (Telephone)
+46 431 45 82 25 (FAX)

Contact: Allan White (Official Correspondent)
HemoCue, Inc.
40 Empire Drive
Lake Forest, CA 92630-2244
(800) 881-1611 x110 (Telephone)
(949) 859-3066 (FAX)
allan@hemocue.com

Date of Preparation: November 18, 2005

Proprietary Name: HemoCue Albumin 201 analyzing system

Classification Name: Automated Urinalysis System

Common Name: HemoCue Albumin 201

Equivalent to: Clinitek 50 Urine Chemistry Analyzer

Microcuvette: Regulation Number = 862.1645
Product Code = JIQ
Classification = Class 1, exempt

Description

The HemoCue Albumin 201 analyzing system consists of a small and portable analyzer and plastic microcuvettes. The microcuvette contains reagents deposited on its inner walls. The urine sample is drawn into the cavity by capillary action. The filled cuvette is inserted into the HemoCue Albumin 201Analyzer where the contents of the cuvette are mixed through vibration. Within 90 seconds, the immunochemical reaction is completed and the turbidity is measured photometrically at 610 nm. The albumin concentration is proportional to the turbidity. When the end point is reached, the result is displayed in mg/L.

Intended Use

The quantitative, rapid, turbidimetric immunoassay of albumin in human urine using a specially designed analyzer, the HemoCue Albumin 201 analyzer. The system can be used for the quantitative determination of low levels of albumin in urine for the purpose of screening for, diagnosing, monitoring and to supplement the clinical evidence in the treatment of microalbuminuria. The system is designed for testing using spot samples or timed collections. A quantitative result is obtained within 90 seconds. HemoCue Urine

Albumin Microcuvettes are for in vitro diagnostic use only. The HemoCue Albumin 201 Analyzer is only to be used with HemoCue Urine Albumin Microcuvettes.
For professional use only.

Technological Characteristics

The HemoCue Albumin 201 assay employs an immunoassay for the microalbumin test. The reagents are contained in the microcuvette. The sample is drawn into the microcuvette by capillary force after which the microcuvettes are inserted into the analyzer for measuring. The HemoCue Albumin 201 Analyzer controls the reaction steps and automatically performs all the measurements and calculations. Results are displayed on the instrument screen. The system is factory calibrated.

Assessment of Performance

Studies were conducted in-house and in clinical settings to demonstrate the performance of the HemoCue Albumin 201 analyzing system and that the intended user can easily operate the system and obtain urinalysis results as the predicate device.

Conclusion

The HemoCue Albumin 201 analyzing system is a convenient method for measuring microalbumin in urine and can be used by typical users and provide clinical results comparable to other test methods in current clinical laboratory and point-of-care practices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 17 2006

HemoCue AB
c/o Mr. Allan White
HemoCue, Inc.
40 Empire Drive
Lake Forest, CA 92630-2244

Re: k053253
Trade/Device Name: HemoCue Albumin 201 Analyzer
Regulation Number: 21 CFR 862.2900
Regulation Name: Automated Urinalysis System
Regulatory Class: Class I
Product Code: KQO, JIQ
Dated: January 25, 2006
Received: January 26, 2006

Dear Mr. White

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053253

Device Name: HemoCue Albumin 201 analyzer

Indications For Use:

The quantitative, rapid, turbidimetric immunoassay of albumin in human urine using a specially designed system, the HemoCue Albumin 201 System. The system is designed be used for the quantitative determination of low levels of albumin in urine at the **point-of-care** for the purpose of screening for, diagnosing, monitoring and to supplement the clinical evidence in the treatment of microalbuminuria. The system is designed for testing using spot samples or timed collections. A quantitative result is obtained within 90 seconds. HemoCue Urine Albumin Microcuvettes are for in vitro diagnostic use only. The HemoCue Albumin 201 Analyzer is only to be used with HemoCue Urine Albumin Microcuvettes.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

K053253