K061812

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5. 510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for a determination of substantial equivalence
1) 510(k)-Nr.	
2) Submitter	Analyticon Biotechnologies AG Am Mühlenberg 10 35104 Lichtenfels Germany Phone +49-6454-7991-0 FAX: +49-6454-7991-30 e-mail: info@analyticon.de www.analyticon.de Contact Person: Dr. Klaus Langer Representative in USA: Kamm & Associates 333 Milford Road, 60015 Deerfield, IL
2) Device Name	Proprietary Name: Combi Scan 500 Common Name: Automated Urine Analyzer Classification Name: Class I (exempt) 21CFR§862.2900: Automated Urine Analyzer (KQO) Additional Classification: Class II: 21CFR§862.1340 Urinary Glucose (nonquant.) test system (JIL) 21CFR§864.6550 Occult Blood test (JIP) Class I exempt: 21CFR§862.1095 Ascorbic acid test system (JMA) 21CFR§862.1115 Urinary bilirubin and its conjugates (nonquant.) test system (JJB) 21CFR§862.1435 Ketones (nonquant.) test system (JIN) 21CFR§862.1510 Nitrite (nonquant.) test system (JMT) 21CFR§862.1550 Urinary pH (nonquant.) test system (CEN) 21CFR§862.1645 Urinary protein or albumin (nonquant.) test system (JIR) 21CFR§862.1785 Urinary urobilinogen (nonquant.) test system (CDM) 21CFR§864.7675 Leukocyte peroxidase test
3) Predicative Device	Clinitec 50 (+ Multistix), Bayer (KQO) 510(k)-Nr. K960546

510(k) Submission Combi Scan 500
5. 510(k) Summary

4) Device Description	The Combi Scan 500 is a medium automated urine test strip analyser for use with Combi Screen test strips to determine one or more of the following parameters from urine: ascorbic acid, bilirubin, blood, glucose, ketones, leucocytes, nitrite, pH, protein, specific gravity. For professional use only!
5) Intended Use	Instrument for measurement of urine test strips Combi Screen for in-vitro determination of Ascorbic acid, Bilirubin, Blood, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein, Specific Gravity, and Urobilinogen from urine. For professional use, not for self testing.
6) Comparison to predicative device	The table below shows similarities and differences to the predicative device

Feature	Combi Scan 500	Clinitek 50
Intended use	Instrument for measurement of urine test strips Combi Screen for in-vitro determination of Ascorbic acid, Bilirubin, Blood, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein, Specific Gravity, and Urobilinogen from urine. For professional use, not for self testing.	The Clinitek 50 urine chemistry analyser is for use with Bayer reagent strips for the determination of glucose, bilirubin, ketone, blood, protein, urobilinogen, nitrite and leucocytes in urine, urine pH, specific gravity and colour. Thje tests on bayer Reagent strips and urine color are considered routine urinalysis.
General design	Bench-top instrument	Bench-top instrument
Energy source	Power transformer Input: 100 - 240 V, 50/60 Hz Output. 7,5V, 3,0 A	Power transformer Input: 100 - 250 V, 50/60 Hz Output. 9V, 2,78 A
Measurement technology	The instrument measures the color of the light that is reflected from the test pads on the strip (reflectometric evauation). These data are converted into meaningful results.	The instrument measures the color and amount of light that is reflected from the test pads on the strip (reflectometric measurement). It then converts these measurements to meaningful results.
Measuring operation	The test strip is dipped into the urine and placed on a conveyor, which moves the strip into the instrument. The instrument controls the incubation time and does the measurement.	The test strip is dipped into the urine and placed on the strip holder in front of the instrument. Then, the strip holder is moved into the instrument, which controls the incubation time and does the measurement.
Analytes	Test strip Combi Screen 11SYS: Ascorbic acid, Bilirubin, Blood, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein, Specific Gravity, and Urobilinogen from urine.	Test strip Multistix 10SG: Bilirubin, Blood, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein, Specific Gravity, and Urobilinogen from urine.
Controlling of the system	LCD-Display, buttons below the display to control the instrument.	LCD-Display, buttons below the display to control the instrument.
Storage of results	Storage of 999 measurements possible	Storage of measurements possible
Printing of results	Printout with results, date & time on thermal paper by internal printer	Printout with results, date & time on thermal paper by internal printer

7) Statement of substantially equivalence	Analyticon has submitted Information that shows the substantial equivalence to the predicative device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Analyticon Biotechnologies AG
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Underwriters Laboratories Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park,
NC 27709-3995

APR - 6 2007

Re: k061812
Trade/Device Name: Combi Scan 500
Regulation Number: 21 CFR §862.1340
Regulation Name: Urinary glucose (non-quantitative) test system.
Regulatory Class: Class II
Product Code: JIL, JIO, JMA, LJX, JRE, CEN, JMT, JIR, JIN, CDM, JJB & KQO
Dated: March 21, 2007
Received: March 22, 2007

Dear Mr. Rongero:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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): K061812

Device Name: Combi Scan 500

Indications For Use:

The Combi Scan 500 is for use with Combi Screen test strips to determine the following parameters from urine: ascorbic acid, bilirubin, blood, glucose, ketones, leucocytes, nitrite, pH, protein, specific gravity, urobilinogen. These measurements are used in the evaluation of diabetes, liver diseases, haemolytic diseases, urogenital and kidney disorders or metabolic abnormalities. For professional use only, not for self testing!

Prescription Use ___X___ AND/OR Over-The-Counter Use __NA___
(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
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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