K023885

OCT 2 1 2003

EXHIBIT 2

ANALYTICON Biotechnologies AG
Am Mühlenberg 10
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Germany
Phone: 49-6454-7991-0
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November 20, 2002

Contact: Umesh Bhalla, Vice President

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name Combi-Screen Urine Test Strips (Models 10SL and 11SL)
   Classification Names:
   Regulatory Class: I Product Code: JMA, JJB, JIN, JMT, JIR, CDM, CEN
   Regulatory Class: II Product Code: JIN
   Common/Usual Name: Urine Test Strips

2. Equivalent legally marketed device: Medi-Test Combi 11, K991927, Macherey-Nagel-Duren

3. Indications for Use (intended use) . Model 10SL: For rapid determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH-Value, Specific Gravity, and Leukocytes in urine
   Model 11SL: For rapid determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH-Value, Specific Gravity, Leukocytes, and Ascorbic Acid in urine.

4. Description of the Device: The urine test strips can be used for the determination of the complete chemical urine status with the parameters: bilirubin, blood, ketones, glucose, leukocytes, nitrite, pH-value, protein, urobilinogen. In addition the specific gravity can be tested. With it early symptoms of three great groups of diseases can be indicated:
   * Disorders of the carbohydrate metabolism (diabetes)
   * Illness of the kidney and urinary passages (e.g. infections of urinary passages, tumors, glomerulonephritis, pyelonephritis)
   * Illness of liver and haemolytic disorders.

5. Safety and Effectiveness, comparisons to predicate devices:
   Medi-Test Combi 11, K991927, Macherey-Nagel-Duren

Characteristic	Medi-Test Combi 11, K991927, Macherey-Nagel-Duren	Combi-Screen®
Indication	For rapid determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH-Value, Specific Gravity, Leukocytes, and Ascorbic Acid in urine.	SAME (Model 10SL does not have the Ascorbic Acid test)
Method	Dip in urine, check against color chart	SAME
Time	60 Sec	SAME

6. Conclusion: The Combi-Screen® has intended use and technological characteristics that are nearly identical to the predicate device. The results of studies and comparisons show the equal properties of the Combi-Screen test strips and of others market urine test strips in principle. The results of the accuracy study show that the test strips Combi-Screen have got the equal properties in principle like the test strips of the manufacturers: Roche, Dade-Behring, Bayer, Macherey- Nagel. They did not observe any false-negative or false-positive results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 1 2003

Analyticon Biotechnologies AG
c/o Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: k023885
Trade/Device Name: Combi-Screen Urine Test Strips (Models 10SL and 11SL)
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL; JIP
Dated: July 23, 2003
Received: July 25, 2003

Dear Mr. Kamm:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K023885

Device Name: Combi-Screen Urine Test Strips (Models 10SL and 11SL)

Indications for Use: Combi-Screen Urine Test Strips

Model 10SL: For rapid determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH-Value, Specific Gravity, and Leukocytes in urine

Model 11SL: For rapid determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH-Value, Specific Gravity, Leukocytes, and Ascorbic Acid in urine

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K023885