K031947

DEC 1 9 2003

Appendix A
Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. **Submitters Information**

Contact person:	Mary E. Gray, RAC NPT Regulatory Affairs Manager
Address:	Bayer Healthcare, LLC A subsidiary of Bayer Corporation 63 North Street Medfield, MA 02052
Phone:	(508) 359-3826
e-mail address:	mary.gray.b@bayer.com
Date Summary Prepared:	June 20, 2003

2. **Device Information**

Proprietary Name:	Clinitek Status Urinalysis Instrument
Common Name:	Urine chemistry analyzer
Classification Name:	Automated urinalysis system
Classification Number:	21 CFR 862.2900, Class I
Classification Panel:	Clinical Chemistry and Clinical Toxicology

3. **Predicate Device Information**

Device Name:	Clinitek 50	Multistix Pro	Multistix 10 SG	Clinitek Microalbumin
Manufacturer:	Bayer Healthcare, LLC	Bayer Corporation	Bayer Corporation	Bayer Corporation
510(k) Number:	# K960546	# K992257	# K905396	# K972706

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4. **Device Description**

The Clinitek Status® Urine Chemistry Analyzer is a portable, easy to use instrument which reads Bayer urine reagent test strips (Multistix® brand), for testing in the clinical laboratory.

The Clinitek Status reports semi-quantitatively assays for 12 urine analytes [albumin (protein-low), bilirubin, blood (occult), creatinine, glucose, ketone, leukocyte, nitrite, pH, protein (protein-high), specific gravity, and urobilinogen]. Reagent strip results are automatically displayed on the Clinitek Status in one (1) minute. A printed hardcopy can also be created either from the results screen or recalled from memory.

The analyzer features a display, internal printer, a serial computer interface, and either electrical outlet or battery operation. Communication between the operator and the analyzer is made through the display using the user interface touch screen on the front surface of the instrument.

The instrument performs a "self-test" and calibration each time the instrument is turned on. Each time a test is run the analyzer re-calibrates using a white plastic calibration bar located at the back of the test strip table.

5. **Statement of Intended Use**

The Clinitek Status® Urine Chemistry Analyzer is a portable, easy to use instrument which reads Bayer reagent test strips for urinalysis (Multistix® brand reagent strips), for testing in the clinical laboratory.

The automated analyzer is intended for the measurement of the following analytes: glucose, bilirubin, ketone, specific gravity, occult blood, pH, protein, urobilinogen, nitrite, leukocytes, albumin and creatinine.

6. **Summary of Technological Characteristics**

The Clinitek Status instrument is similar in technological characteristics, device performance and intended use therefore is substantially equivalent to the predicate devices, the Clinitek 50 (# **K960546**), visual Multistix 10SG (# **K905396**), Clinitek Microalbumin (# **K972706**) and Multistix PRO 10LS (# **K992257**).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2003

Mary E. Gray, RAC
NPT Regulatory Affairs Manager
Bayer HealthCare LLC
Diagnostics Division
63 North Street
Medfield, MA 02052

Re: k031947
Trade/Device Name: Bayer Clinitek Status® Urine Chemistry Analyzer
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY, JIL, JIP, KQO
Dated: October 8, 2003
Received: October 9, 2003

Dear Ms. Gray:

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). Other general information on your responsibilities under the Act may be obtained 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K031947

Device Name: Bayer Clinitek Status® Urine Chemistry Analyzer

Indications for Use:

The CLINITEK Status® Urine Chemistry Analyzer is a portable, easy to use instrument which reads Bayer reagent test strips for urinalysis (Multistix® brand reagent strips), for testing in the clinical laboratory.

The automated analyzer is intended for the measurement of the following analytes: glucose, bilirubin, ketone, specific gravity, occult blood, pH, protein, urobilinogen, nitrite, leukocytes, albumin and creatinine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031947