**510(k) Summary - updated**

K091216

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

**Submitter information**


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OCT - 9 2009


Phone: 781-269-3401


Date summary prepared: September 25, 2009

**Device Information**

Proprietary Name: Clinitek Status®+ Analyzer
Clinitek Status® Connect System

Common name: Urine Chemistry Analyzer

Main classification name: Automated Urinalysis System

Main classification number: 21 CFR 862.2900, Class I

Main classification panel: Clinical Chemistry and Clinical Toxicology

**Predicate Devices**

| Element | Predicate Device |
|---|---|
| Device Name | Clinitek Status |
| Common name | Urine Chemistry Analyzer |
| 510(k) Number | K031947 and K032563 |
| Manufacturer | Siemens Healthcare Diagnostics Limited |

**Device Description**

The Clinitek Status®+ Analyzer, a device modification to the current Clinitek Status®, is a portable easy to use urine chemistry analyzer. It is designed to read only Siemens Reagent Strips for Urinalysis and Clinitest® hCG tests.

Identical to the Clinitek Status Analyzer, the Clinitek Status+ analyzer is intended for the measurement of the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-

to-Creatinine Ratio, Specific Gravity, Urobilinogen, and human Chorionic Gonadotropin (hCG).

The enhanced Analyzer identifies automatically all instrument-read Siemens strip types and adds a quality check to assess if the strip has been compromised by humidity exposure.

In addition, the enhanced Analyzer provides reporting flexibility by allowing users to select specific test parameters to report from on a given strip and provides enhanced security to allow for user/operator access restrictions.

When the connector is attached to the enhanced analyzer (Clinitek Status+), the model is referred to as Clinitek Status Connect System. Additional functionality is enabled including bar code data entry, quality control management, and connectivity to hospital network.

## Statement of Intended Use

The Clinitek Status®+ Analyzer Urine Chemistry Analyzer is a portable easy to use analyzer. It is designed to read only Siemens Reagent Strips for Urinalysis and Clinitest® hCG tests.

This analyzer is intended for the measurement of the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, Urobilinogen, and human Chorionic Gonadotropin (hCG).

These measurements are used to assist diagnosis in the following areas:

- Kidney Function
- Urinary tract infections
- Metabolic disorders (e.g. diabetes mellitus)
- Liver Function
- Pregnancy

Tests performed using the Clinitek Status®+ Analyzer are intended for *in vitro* diagnostic use only.

The Clinitek Status®+ Analyzer is intended for near patient (point-of-care) facilities and centralized laboratory locations.

## Summary of Technological Characteristics

The Clinitek Status+ and Clinitek Status Connect System operating principle, technical platform, instrument and reagent analytical method, and intended use remain the same as the current Clinitek Status analyzer. In addition, it uses the same test strips and cassettes currently used on the Clinitek Status analyzer.

The optical system consists of six light emitting diodes, a light guide, a mirror, a lens and a detector. Light from the LEDs travels along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror. It is then directed through an aperture on the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

**Assessment of Performance**

An internal study was conducted to demonstrate the performance of the Clinitek Status+ Analyzer and Clinitek Status Connect System (modified device) and assess its substantial equivalence against the Clinitek Status (predicate device).
The scope of the study covered the impact of the proposed software enhancements on performance with both urinalysis strips (Multistix® 10SG) and hCG cassettes (Clinitest® hCG).

Over the study duration, 150 urine specimens were evaluated. The testing was performed to ensure that the software enhancement has not impacted current performance. Based on data analysis, the Urinalysis method comparison results for all 5 of the test conditions meet prescribed performance requirements for percent positive agreement (relative sensitivity) and percent negative agreement (relative specificity) relative to the predicate device (Clinitek Status). Also, performance for both hCG levels tested meet prescribed limits.

In addition information on Software Development Life Cycle including software requirements specifications, risk management report, and overall verification and validation plans were included to provide additional assurance of device performance.

**Conclusion**

In conclusion, the modified device (Clinitek Status+ and Clinitek Status Connect System) has the same Technological Characteristics and Intended Use as the predicate. The data presented is a summary of risk management activities, internal laboratory performance evaluation and software development information which all provide assurance that the modified device is substantially equivalent to the currently marketed Clinitek Status.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics
c/o Noor Malki
Senior Manager, Regulatory Affairs (POC & Walpole sites)
2 Edgewater Drive,
Norwood, MA 02062

OCT – 9 2009

Re: k091216
Trade/Device Name: Clinitek Status+Analyzer And Clinitek Status Connect System, Models 1780, 1797
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system.
Regulatory Class: II
Product Code: JIL, JIP, JHI, JFY, JIR, JJB, JIN, LJX, JMT, CEN, JRE, CDM, KQO
Dated: September 25, 2009
Received: October 1, 2009

Dear: Ms. Malki:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): K091216

Device Name: Clinitek Status®+ Analyzer
Clinitek Status® Connect System *(consist of Clinitek Status®+ Analyzer with Connector attached).*

Indication For Use:

The Clinitek Status®+ Urine Chemistry Analyzer is a portable easy to use analyzer. It is designed to read only Siemens Reagent Strips for Urinalysis and Clinitest® hCG tests.

This analyzer is intended for the measurement of the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, Urobilinogen, and human Chorionic Gonadotropin (hCG).

These measurements are used to assist diagnosis in the following areas:

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Tests performed using the Clinitek Status®+ Analyzer are intended for *in vitro* diagnostic use only.

The Clinitek Status®+ Analyzer is intended for near patient (point-of-care) facilities and centralized laboratory locations.

| Prescription Use _X_ | And/Or | Over the Counter Use ____. |
|---|---|---|
| (21 CFR Part 801 Subpart D) | | (21 CFR Part 801 Subpart C) |

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 091216