K093555

APR - 2 2010

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521- 4569

Contact Person: Jennifer Tribbett
Date Prepared: March 24, 2010

Device Name

Proprietary name: (1) Chemstrip 10 UA
(2) cobas u 411 Urine Analyzer

Common name: (1) Reagent Strip for urinalysis
(2) Automated Urinalysis System

Classification name: (1) Urinary glucose, ketones, nitrite, protein, blood, bilirubin, urobilinogen, leukocytes, pH and specific gravity
(2) Automated Urinalysis System

Classification

The FDA has classified the devices as follows;

Classification Name	Classification Number	Panel Name	Exempt	Device Class	Regulation Citation
Method, enzymatic, glucose (urinary, non-quantitative)	JIL	75 Clinical Chemistry	NO	II	21 CFR 862.1340
Blood, occult, colormetric, in urine	JIO	82 Hematology	NO	II	21 CFR 864.6550

Classification Name	Classification Number	Panel Name	Exempt	Device Class	Regulation Citation
Diazonium Colorimetry, urobilinogen (urinary, non-quant)	CDM	75 Clinical Chemistry	YES	I	21 CFR 862.1785
Dye-Indicator, pH (Urinary, non-quant)	CEN	75 Clinical Chemistry	YES	I	21 CFR 862.1550
Nitroprusside, ketones (urinary, non-quant)	JIN	75 Clinical Chemistry	YES	I	21 CFR 862.1435
Indicator method, protein or albumin (urinary, non-quant)	JIR	75 Clinical Chemistry	YES	I	21 CFR 862.1645
Diazo (colormetric), Nitrite (Urinary, non-quant)	JMT	75 Clinical Chemistry	YES	I	21 CFR 862.1510
Test, Urine Leukocyte	LJX	82 Hematology	YES	I	21 CFR 864.7675
Azo-dyes, colormetric, bilirubin & its con	JJB	75 Clinical Chemistry	YES	I	21 CFR 862.1115
Automated Urinalysis System	KQO	75 Clinical Chemistry	YES	I	21 CFR 862.2900
Refractometer for clinical use	JRE	75 Clinical Chemistry	YES	I	21 CFR 862.2800

Substantial equivalence

The cobas u 411 urinalysis test system is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Chemstrip Urine Analyzer (K921087 and K931602). Both instruments are designed to provide semi-quantitative results using a reagent strip that includes test pads for determination of pH, leukocytes, blood, nitrite, protein, glucose, ketone, urobilinogen, bilirubin, and specific gravity.

Device Description

The cobas u 411 urine analyzer is a semi-automated, benchtop analyzer which is designed to read Chemstrip 10 UA (Combur^{10} Test M) test strips for urinalysis for the measurement of bilirubin, blood, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen and color (if selected). These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Tests performed using the cobas u411 are intended for prescription, in vitro diagnostic use only.

The functions of the cobas u 411 analyzer includes:

- o Sample identification (with optional barcode scanner)
- o Controlled incubation period
- o Photometric measurements
- o Result memory
- o Optional formats for data output

Comparative Tables

The following table compares the cobas u 411 urinalysis test system with the predicate device. These represent the features that are the same for both systems.

Feature	Chemstrip Urine Analyzer (predicate)	cobas u 411 urinalysis test system (proposed)
Intended Use	The Chemstrip Urine Analyzer is a semiautomated, computerized analyzer intended for the in vitro semi-quantitative determination of urine analytes, including specific gravity (SG), pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and erythrocytes Note: A compensation pad is provided to aid in the correction of interference from the intrinsic color of urine.	The cobas u 411 urine analyzer is a semi-automated, benchtop analyzer which is designed to read Chemstrip 10 UA (Combur^{10} Test M) test strips for urinalysis for the measurement of bilirubin, blood, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen and color (if selected). These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Tests performed using the cobas u411 are intended for prescription, in vitro diagnostic use only.
Analyzer Technology	Reflectance photometry	Same
Light Source	LEDs	Same
Reagent Strip	Chemstrip 10 UA test strip	Same
Urine application	Test strip dipped into urine sample	Same
Intrinsic color compensation	The test strip area not impregnated with reagents, allows instrumental compensation for the intrinsic color of the urine while testing.	Same
Calibration method	Calibration strips with specific reflectance values for calibration.	Same

Feature	Chemstrip Urine Analyzer (predicate)	cobas u 411 urinalysis test system (proposed)
Test Principle	**pH:** color change with the indicators methyl red and bromthymol blue. **Leukocytes:** esterase cleaves an indoxyl ester, and the indoxyl reacts with a diazonium salt to produce a purple color. **Nitrite:** based on the principle of the Griess test. Nitrite, if present, reacts with an aromatic amine to give a diazonium salt which yields a red-violet azo dye. **Protein:** based on the "protein error of pH indicators" involving tetrachlorophenol-tetrabromosulfophthalein **Glucose:** based on the specific glucose oxidase/peroxidase reaction (GOD/POD method). **Ketone:** based on the principle of Legal's test involving use of sodium nitroprusside. **Urobilinogen:** Urobilinogen is coupled with 4-methoxybenzene-diazonium-tetrafluoroborate in an acid medium to form a red azo dye. **Bilirubin:** based on the coupling of bilirubin with a diazonium salt. **Blood:** The peroxidase-like action of hgb and myoglobin catalyzes the oxidation of the indicator by the organic peroxide. **Specific Gravity:** In the presence of cations, protons are released by a complexing agent in the test and produce a color change.	Same

Comparative Tables

The following table compares the cobas u 411 urinalysis test system with the predicate device. These represent the key features that are different between the two system.

Feature	Chemstrip Urine Analyzer (predicate)	cobas u 411 urinalysis test system (proposed)
Measuring Unit	Light Emitting Diodes (LEDs) Wavelength: Orange: 620 nm Green: 555 nm Red: 660 nm Reader Head: 2 heads with 3 LEDs each	Light Emitting Diodes (LEDs) Wavelength: Orange: 620 nm Green: 555 nm Blue: 470 nm Sensor: 11 wide range photo sensors
Operating Conditions	Temperature: •operational: 15 – 34 °C •storage: -20 – 60 °C Humidity: •operational: 20 – 80% •storage: 20 – 95%	Temperature: •operational: 15 – 32 °C •storage: -25 – 60 °C Humidity: •operational: 30 – 80% •storage: 10 – 95%
Storage Medium	Floppy Disks	USB Stick
Strip Detector	One strip detector	Two strip detectors

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Roche Diagnostics Corporation
c/o Ms. Jennifer Tribbett
9115 Hague Road
Indianapolis, Indiana 46250

APR 02 2010

Re: k093555
Trade Name: Cobas u 411 Test System
Regulation Number: 21 CFR §862.1340
Regulation Name: Urinary Glucose (non-quantitative test system)
Regulatory Class: Class II
Product Codes: JIL, JIO, CDM, CEN, JIN, JIR, JMT, JJB, LJX, CEN, JRE, KQO
Dated: March 29, 2010
Received: March 30, 2010

Dear Ms. Tribbett:

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

Indications for Use Form

510(k) Number (if known):

Device Name: **cobas u 411 Urinalysis Test System**

Indications For Use:

The cobas u 411 urine analyzer is a semi-automated, benchtop analyzer which is designed to read the Chemstrip 10 UA (Combur^{10} Test M) test strips for urinalysis for the measurement of bilirubin, blood, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen and color (if selected). These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Tests performed using the cobas u411 are intended for prescription, in vitro diagnostic use only.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

510(k) K093555