510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: K032437

B. Analyte: Chemstrip 5OB, 7, and 10MD test strips for the Chemstrip 101 Urine Analyzer and Criterion II Urine Analyzer

C. Type of Test: Reflectance, colorimetric

D. Applicant: Roche Diagnostics

E. Proprietary and Established Names: Chemstrip 5OB, Chemstrip 7, and Chemstrip 10 MD, Urinary test system

F. Regulatory Information:

1. Regulation section: Refractometer - 21 CFR 862.2800, Urinary pH – 21 CRR 862.1550, Urinary Leukocytes – 21 CFR 864.7675, Urinary Occult Blood – 21 CFR 864.6550, Urinary Nitrite – 21 CFR 862.1510, Urinary Ketones – 21 CFR 862.1435, Urinary bilirubin and its conjugates – 21 CFR 862.1115, Urinary Urobilinogen – 21 CFR 862.1785, Urinary protein – 21 CFR 1645, Urinary glucose - 21 CFR 862.1340

2. Classification: Refractometer – Class I exempt, Urinary pH – Class I exempt, Urinary Leukocytes – Class I exempt , Urinary Occult Blood – Class II, Urinary Nitrite – Class I exempt , Urinary Ketones – Class I exempt , Urinary bilirubin and its conjugates – Class I exempt , Urinary Urobilinogen – Class I exempt, Urinary protein Class I exempt, Urinary glucose - Class II

3. Product Code: Refractometer – JRE, Urinary pH – CEN, Urinary Leukocytes – LJX, Urinary Occult Blood – JIO, Urinary Nitrite – JMT , Urinary Ketones – JIN , Urinary bilirubin and its conjugates – JJB , Urinary Urobilinogen – CDM, Urinary protein – JIR, Urinary glucose - JIL

4. Panel: All 75

G. Intended Use:

1. Intended use(s): Multi-parameter test strips to measure certain constituents in the urine either visually or by using the Roche Diagnostics Chemstrip 101 Urine Analyzer or Criterion II Urine analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Chemstrip 5OB, 7 and 10 MD urine test strips are inert plastic strips to which are attached different reagent pads for determining specific gravity, pH, indication leukocytes, nitrite, protein, glucose, ketones, urobililinogen, bilirubin, blood and hemoglobin in urine.

2. Indication(s) for use: Multi-parameter test strips to measure certain constituents in the urine either visually or by using the Roche Diagnostics Chemstrip 101 Urine Analyzer or Criterion II Urine analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Chemstrip 5OB, 7 and 10 MD urine test strips are inert plastic strips to which are attached different reagent pads for determining specific gravity, pH, indication leukocytes, nitrite, protein, glucose, ketones, urobililinogen, bilirubin, blood and hemoglobin in urine.

3. Special condition for use statement(s): none given

4. Special instrument Requirements: visual determination or via Roche Diagnostics Chemstrip 101 Urine Analyzer or Criterion II Urine analyzer

H. Device Description: The Chemstrip 5 OB test strip is a multi-parameter urinalysis test strip, which measures leukocytes, blood/hemoglobin, nitrite, protein and glucose in the urine.

The Chemstrip 7 test strip is a multi-parameter urinalysis test strip, which measures pH, ketone, leukocytes, blood/hemoglobin, nitrite, protein and glucose in the urine.

The Chemstrip 10 MD test strip is a multi-parameter urinalysis test strip, which measures specific gravity, pH, ketone, leukocytes, blood/hemoglobin, nitrite, protein, urobilinogen, bilirubin and glucose in the urine.

I. Substantial Equivalence Information:

1. Predicate device name(s): Bayer Multistix 10 SG for use on the Clinitek 50 Urine Analyzer and Chemstrip 10MD test strip for use on the Chemstrip 101 Urine Analyzer or the Criterion II analyzer.

2. Predicate K number(s): Bayer Multistix 10 SG for use on the Clinitek 50 Urine Analyzer – K960546 and Chemstrip 10MD test strip for use on the Chemstrip 101 Urine Analyzer – K983510.

3. Comparison with predicate:

Similarities and Differences		
Item	**Device**	**Predicate**
	Chemstrip 5 OB & 7 Test Strips for the Chemstrip 101 Urine Analyzer	Chemstrip 10MD test strip for use on the Chemstrip 101 Urine Analyzer.
Intended use	Same	The Chemstrip 10 MD urine test strip is a multiparameter test strip used to measure

		certain constituents in the urine either visibly or on the Roche Diagnostics Chemstrip 101 Urine Analyzer. These \measurements are used in the evaluation of renal, urinary and metabolic disorders.
Constituents Detected	Reduced number of parameters	Specific Gravity, Leukocytes, Nitrite, pH, Protein, Glucose, Ketones, Urobilinogen, Bilirubin, Blood
Test principle	Not Offered on the 5 or 7	Specific Gravity: In the presence of cations, protons are released by a complexing agent and produce a color change of the bromthymol blue indicator.
Test principle	Same	Leukocytes: Leukocytes in urine are detected by the action of esterase, present in granulocytic leukocytes, which catalyzes the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a color change.
Test principle	Same	Nitrite: Nitrite reacts with an aromatic amine to give a diazonium salt, which by coupling with a further compound, yields a red-violet azo dye.
Test principle	Same on the 7 but not offered on the 5	pH: The test strip contains the indicators methyl red and bromthymol blue.

		These give clearly distinguishable colors over the pH range of 5 – 9.
Test principle	Same	Protein: The detection of protein is based on the "protein error of pH indicators". The indicator 3',3",5',5"-tetrachlorophenol-3,4,5,6-tetrabromosulfophtalein yields a color change in a positive reaction
Test principle	Same	
Test principle	Same	Glucose: Glucose Detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method.
Test principle	Same on the 7 not offered on the 5	Ketones: Sodium nitroprusside and glycine react with acetoacetate and acetone in an alkaline medium to form a violet dye complex.
Test principle	Not offered on the 5 or 7	Urobilinogen: Urobilinogen is coupled with 4-methoxybenzene-diazoniun-tetrafluoroborate in an acid medium to form a red azo dye.
Test principle	Not offered on the 5 or 7	Bilirubin; Bilirubin detection is based on the coupling reaction of a diazonuium salt with bilirubin in an acid medium which yields a color change
Test principle	Same	Blood: The chemical detection of blood is based on the strong pseudoperoxidase action of erythrocytes and hemoglobin. Hemoglobin

		and myoglobin, if present, catalyze the oxidation of the indicator by the organic peroxide contained on the test paper and the liberated hemoglobin produces a green dot.
Test Pad	Same	The test papers are attached to the strip with a nylon mesh and certain test papers have an inert absorbent paper located between the test area and the strip.

Similarities and Differences		
Item	**Device**	**Predicate**
	Chemstrip 5 OB, 7 Test and 10 MD Strips for the Chemstrip 101 Urine Analyzer	Bayer Multistix 10 SG for use on the Clinitek 50 Urine Analyzer.
Intended use	Multi-parameter test strips to measure certain constituents in the urine either visually or by using the Roche Diagnostics Chemstrip 101 Urine Analyzer or Criterion II Urine analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Chemstrip 5OB, 7 and 10 MD urine test strips are inert plastic strips to which are attached different reagent pads for determining specific gravity, pH, indication leukocytes, nitrite, protein, glucose, ketones,	Same

	urobililinogen, bilirubin, blood and hemoglobin in urine.	
Constituents detected	Combinations of specific gravity, pH, indication leukocytes, nitrite, protein, glucose, ketones, urobililinogen, bilirubin, blood and hemoglobin in urine.	Same

J. Standard/Guidance Document Referenced (if applicable): None Stated

K. Test Principle: Chemstrip 5OB, 7 and 10 MD urine test strips are inert plastic strips to which are attached different reagent pads for determining specific gravity, pH, indication leukocytes, nitrite, protein, glucose, ketones, urobililinogen, bilirubin, blood and hemoglobin in urine.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility: This study used a total of nine chemstrip 101 analyzers – three analyzers per strip type. In general, each strip was run on each of the nine analyzers 34 times using two lot numbers of test strips (n=17 per lot number); however, there were some exceptions to this procedure.

Ketones were only run on the analyzers designated for the Chemstrip 7 and Chemstrip 10 MD test strips because they are not present on the Chemstrip 5 OB test strips. The urobilinogen and bilirubin were only run on the analyzers designated for the Chemstrip 10MD test strips because they are not available on the Chemstrip 5OB and Chemstrip 7 test strips.

All data (except for quality control data) was collected in reflectance mode. These reflectance values are used to set the appropriate borders for the urine strips on the Chemstrip 101 analyzers in order to establish the sensitivity ranges claimed for the test strips.

Acceptance criteria – When choosing borders for the urine test strips, the majority of the borders were chosen such that at the mid-range of the sensitivity claim approximately 50% of the results would be positive.

The new sensitivity claims are Leukocytes 30 – 35 Leu/uL, Protein 25-32 mg/dL, Glucose 30 – 40 mg/dL, Nitrite 0.06 – 0.10 mg/dL, Ketones 5

-15 mg/dL, Blood 5 – 20 Ery/uL, Urobilinogen 1 – 2 mg/dL, Bilirubin 0.8 – 1.5 mg/dL. Sensitivity claims were not revised for the Criterion II, the sensitivity for the Criterion are provided under K954024. Bilirubin was changed a few years ago to reflect a more conservative claim of 1.0 for the Criterion.

b. Linearity/assay reportable range: A negative urine pool was used for each analyte and was tested on the Chemstrip 101 and Criterion II and controls were run to check performance. When evaluating the possible borders, the negative urine samples were also used. No urine samples were specifically targeted as negative for a particular analyte. Each analyte was spiked separately so that other results from that urine sample would be negative. Those results were used to determine what the reflectance values would be if the sample were negative.

c. Traceability (controls, calibrators, or method): A negative urine pool was used for each analyte and was tested on the Chemstrip 101 and Criterion II and controls were run to check performance.

Detection limit: Acceptance criteria – When choosing borders for the urine test strips, the majority of the borders were chosen such that at the mid-range of the sensitivity claim approximately 50% of the results would be positive.

Analytical specificity: Interfering substances and limitations of each reagent on the strip are listed as follows. pH – There are no know interferents. Leukocyte test – The drugs cephalexin and gentamicin are show to interfere. Nitrites are affected by large amounts of ascorbic acid resulting in a decrease of sensitivity. False positive proteins may result in strongly basic urine 9.0 or greater. False negative glucose results may occur in samples with high amounts of ascorbic acid and with oxidizing reagents found in some containers. Ketones are affected by phenolketone or phthalein compounds that may be administered for kidney or liver function tests may produce a red – red orange color which are easily distinguished from colors obtained with ketone bodies. 2-Mercaptoethane sulfonate sodium (MZESNA) or other sulfhydryl containing products may cause false-positive results for ketone bodies. Blood/Hemoglobin test may obtain false negative readings when formalin is used to preserve the urine. Nitrite greater than 10 mg/dl in the urine (rare) delays the reaction of the strip. False positive results may be obtained when residues of strongly oxidizing cleaning agents are found in the urine container. Urine from menstruating females has been found to occasionally yield false positives. Specific gravity may be affected by the measurement methodologies due to their differing principles and limitations. Urines above 1.025 should be measured using a Refractometer. Glucose and urea concentrations greater than 1% may

cause low specific gravity. The presence of moderate protein or ketoacidosis may result in a falsely elevated specific gravity. Urobililinogen total absence cannot be measured. Urine from patients treated with phenoazopyridine may show a false positive. Elevated nitrites or formalin as a preservative may cause a decrease in color reaction. Bilirubin may be affected by large amounts of ascorbic acid following the ingestion of medication containing vitamin C or the ingestion of fruit juices may show less sensitivity. Elevated levels of nitrite may result in lower values. False positives may be produce by medication turning the urine red to red orange (e.g. phenoazopyridine).

Assay cut-off: When choosing borders for the urine test strips, the majority of the borders were chosen such that at the mid-range of the sensitivity claim approximately 50% of the results would be positive.

2. Comparison studies:

   a. Method comparison with predicate device: This study used a total of nine chemstrip 101 analyzers – three analyzers per strip type. In general, each strip was run on each of the nine analyzers 34 times using two lot numbers of test strips (n=17 per lot number); however, there were some exceptions to this procedure.

   Ketones were only run on the analyzers designated for the Chemstrip 7 and Chemstrip 10 MD test strips because they are not present on the Chemstrip 5 OB test strips. The urobilinogen and bilirubin were only run on the analyzers designated for the Chemstrip 10MD test strips because they are not available on the Chemstrip 5OB and Chemstrip 7 test strips.

   All data (except for quality control data) was collected in reflectance mode. These reflectance values are used to set the appropriate borders for the urine strips on the Chemstrip 101 analyzers in order to establish the sensitivity ranges claimed for the test strips.

   b. Matrix comparison: The difference between the predicate device and the new devices consist of the number of analytes present on the strip.

3. Clinical studies:

   a. Clinical sensitivity: none stated

   b. Clinical specificity: none stated

   c. Other clinical supportive data (when a and b are not applicable): none stated

4. Clinical cut-off: none stated

5. Expected values/Reference range: Expected values in a normal urine would result in a negative or zero reading except for pH with an established range of 5.0 – 9.0.

M. Conclusion: I recommend that the Roche Chemstrip 5OB, Chemstrip 7, and Chemstrip 10 MD, Urinary test system are substantially equivalent to their respective predicate devices.