
510(k) SAFETY AND EFFECTIVENESS SUMMARY

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K960546

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Device: Trade Name: CLINITEK 50 Urine Chemistry
Analyzer
Common Name: Urine chemistry analyzer
Document Control Number: K96 _____

Classification Information: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code -- 75 KQO (automated urinalysis system)

Predicate Devices: MULTISTIX® 10-SG Reagent Strips for Urinalysis
(visual readout)
CLINITEK® 200+ Urine Chemistry Analyzer
CLINITEK® ATLAS Urine Chemistry Analyzer

Device Description: The CLINITEK 50 Urine Chemistry Analyzer is a portable reflectance spectrophotometer that instrumentally measures the reflectance off a reacted Bayer Reagent Strip for Urinalysis. The CLINITEK 50 Urine Chemistry Analyzer displays and prints urinalysis results and can be connected to a laboratory computer for data management.

Intended Use: The CLINITEK 50 Urine Chemistry Analyzer is for use with Bayer Reagent Strips for Urinalysis such as MULTISTIX 10-SG Reagent Strips for the determination of glucose, bilirubin, ketone, blood, protein, urobilinogen, nitrite and leukocytes in urine, urine pH, specific gravity and color. The tests provided on Bayer Reagent Strips and urine color are considered routine urinalysis.

Technological Characteristics:

The CLINITEK 50 Urine Chemistry Analyzer is a reflectance spectrophotometer. It has similar technological characteristics to other CLINITEK® Urine Chemistry Analyzers such as the CLINITEK 200+ and CLINITEK ATLAS Analyzers. It is a small, portable instrument which makes it suitable for physician office laboratories. The user manually dips a Bayer Reagent Strip into a urine specimen and places it on the CLINITEK 50 Urine Chemistry Analyzer. The instrument times the reactions on the strip, measures the reflectance off the strip and converts the results to clinically meaningful units that correspond to the color chart on the bottle label of the strip. The urinalysis results are displayed on the instrument and can be printed or transferred to a laboratory computer.

Performance Studies:

Studies were conducted in-house and in clinical settings to demonstrate that the performance of the CLINITEK 50 Urine Chemistry Analyzer is equivalent to the predicate devices and that the intended user can easily operate the instrument and obtain urinalysis results.

Conclusion:

The results of in-house and clinical evaluations of the CLINITEK 50 Urine Chemistry Analyzer demonstrate that the device is equivalent in performance to the predicate devices and suitable for its intended use.
