

## 510(k) Summary

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**Introduction** According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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**1) Submitter name, address, contact** Boehringer Mannheim Corporation  
"doing business as Roche Diagnostics"  
9115 Hague Rd.  
Indianapolis, IN 46250  
(800) 428-5074 ext. 3742

Contact Person: Jennifer Tribbett

Date Prepared: October 5, 1998

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**2) Device name** Proprietary name: Chemstrip 101 Urine Analyzer  
  
Common name: Automated Urinalysis System  
  
Classification name: System, Automated Urinalysis, 75KQO  
Device Class I

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**3) Predicate device** We claim substantial equivalence to the currently marketed Roche Diagnostics, Boehringer Mannheim Chemstrip Mini UA Urine Analyzer.

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## 510(k) Summary, Continued

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**4) Device Description** The Chemstrip 101 Urine Analyzer is a reflectance photometer intended for in-vitro semi-quantitative reading of Chemstrip 10 UA urine test strips for the following analytes: specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood.

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**5) Intended use** In-vitro semi-quantitative determination of urine analytes. This is the same intended use as previously cleared for the Chemstrip Mini Urine Analyzer (K943592).

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**6) Comparison to predicate device:** The table below indicates the similarities between the Chemstrip 101 Urine Analyzer and the predicate device, the Chemstrip Mini UA Urine Analyzer.

Topic	Chemstrip 101 Urine Analyzer	Predicate: Chemstrip Mini UA Urine Analyzer
Intended Use	In-vitro semi-quantitative determination of urine analytes	Same
Scientific Technology	Reflectance Photometer	Same
Urine Test Strips	For use with Chemstrip 10 UA test strips	Same
Test Parameters	Specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood.	Same

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## 510(k) Summary, Continued

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### 6. Comparison to Predicate Device

The Chemstrip 101 Urine Analyzer is a reflectance photometer intended for in-vitro semi-quantitative reading of Chemstrip 10 UA urine test strips for the following analytes: specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, and blood.

The modifications which have been incorporated into the Chemstrip 101 Urine Analyzer are:

- 1.) an additional calibration fail-safe mechanism;
- 2.) an automated test strip holder;
- 3.) a rotating reader head, and
- 4.) increased results memory capacity

#### **Calibration Fail-Safe:**

The Chemstrip 101 contains a fail-safe mechanism which prevents a test from being performed after the weekly instrument calibration limit. The device software will prompt the user, via a message display, to "REPEAT CALIBRATION" every 7 days after the last valid calibration. This fail-safe will not allow the user to run a test strip until calibration is performed.

In the initial (unmodified) analyzer, the "Repeat Calibration" message was also displayed after the 7 day calibration limit, but a lock-out mechanism was not incorporated which prevented the user from performing an actual test.

This modification is an enhanced fail-safe feature.

#### **Automated Test Strip Tray:**

The Chemstrip 101 has eliminated the manual test strip tray by incorporating a motor driven (automated) test strip tray. The user will place the strip on the motorized test tray and the device will automatically move the tray into the instrument for measurement. This modification allows for the automatic positioning of the test strip versus the manual positioning required by the initial (unmodified) analyzer.

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## 510(k) Summary, Continued

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### **F. Device description and comparison**

#### **Reader Head:**

Due to the test strip holder being manual and not automated, the original analyzer had 11 reader channels with fixed positioned Light Emitting Diodes (LEDs). The Chemstrip 101 utilizes the same light source (Light Emitting Diodes) and technology (reflectance photometry) as the original analyzer, but the modified device incorporates one reader head since the strip holder is capable of moving the test strip into position under the LEDs for analyte measurement.

#### **Results Memory Capacity:**

The initial (unmodified) analyzer did not have memory capability. The Chemstrip 101 incorporates the ability to store up to 100 sample results with the option of reprinting the results from memory.



OCT 27 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Jennifer Tribbett  
Regulatory Affairs Consultant  
Boehringer Mannheim  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, Indiana 46250-0457

Re: K983510  
Chemstrip 101 Urine Analyzer  
Regulatory Class: II  
Product Code: KQO, CDM, CEN, JIL, JIN, JIO, JIR, JJB,  
JMT, JRE, LJX  
Dated: October 5, 1998  
Received: October 7, 1998

Dear Ms. Tribbett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

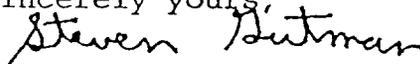
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Roche Diagnostics, Boehringer Mannheim Chemstrip 101 Urine Analyzer

Indications for Use:

The Roche Diagnostics, Boehringer Mannheim Chemstrip 101 Urine Analyzer is a reflectance photometer for in-vitro semi-quantitative determination of the following urine analytes: specific gravity, pH, leukocytes, nitrite, glucose, ketones, urobilinogen, bilirubin and blood.

According to the Code of Federal Regulations, Title 21 (Food and Drugs), Part 862.2900, an automated urinalysis system is a device intended to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis systems. This device is used in conjunction with certain materials to measure a variety of urinary analytes.

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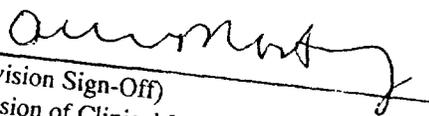
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K983510