



March 14, 2019

Roche Diagnostics/Boehringer Mannheim GmbH
Luann Ochs
9115 Hague Rd.
Indianapolis, IN 46256

Re: k981632

Trade/Device Name: Liquid Total Bilirubin Reagent
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG, MQM
Dated: May 7, 1998
Received: May 8, 1998

Dear Luann Ochs:

This letter corrects our substantially equivalent letter of June 15, 1998.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin Reagent

Indications for Use:

The Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin reagent is intended for use for the quantitative determination of total bilirubin in serum and plasma of adults and neonates. It is for use on automated clinical chemistry analyzers.

According to the Code of Federal Regulations, Title 21 (Food and Drugs), Part 862.1110, a bilirubin (total or direct) test system is a device intended to measure the levels of bilirubin (total or direct) in plasma or serum. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, if used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

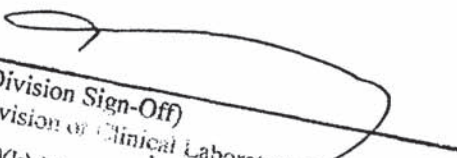
Concurrence of CDRH, Office of Device Evaluation (ODE)

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 KC 981632

JUN 15 1998

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.

1) Submitter name, address, contact Roche Diagnostics, Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Luann Ochs

Date Prepared: May 7, 1998

2) Device name Proprietary name: Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin Reagent

Common name: bilirubin (total or direct) test system

Classification name: Diazo colorimeter, bilirubin, 75CIG
Device Class II

3) Predicate device We claim substantial equivalence to the currently marketed Roche Diagnostics, Boehringer Mannheim Total Bilirubin/DPD reagent system, catalog number 1039034, a modification of the Single Vial DPD Total Bilirubin reagent system, K781921.

4) Device Description Total bilirubin, in the presence of a suitable solubilizing agent, is coupled with a diazonium ion in a strongly acid medium (ph 1 - 2).

Bilirubin + diazonium ion $\xrightarrow{\text{acid}}$ Azobilirubin

The intensity of the color of the azobilirubin formed is proportional to the total bilirubin concentration and can be measured photometrically.

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510(k) Summary, Continued

5) **Intended use** The Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin reagent is intended for use for the quantitative determination of total bilirubin in serum and plasma of adults and neonates. It is for use on automated clinical chemistry analyzers.

6) **Comparison to predicate device** The Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin reagent is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics, Boehringer Mannheim Total Bilirubin/DPD reagent system, catalog number 1039034, a modification of the Single Vial DPD Total Bilirubin reagent system, K781921.

The following table illustrates the similarities between the Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin Reagent and the predicate device. Specific data on the performance of the system have been incorporated into the draft labeling in Section V of this submission. Labeling for the predicate device is provided in Section VI.

Similarities:

Feature	New Liquid Total Bilirubin Reagent	Predicate Total Bilirubin Reagent
Intended Use	Measurement of total bilirubin	Measurement of total bilirubin
Sample Type	Serum or plasma, no preparation required	Serum or plasma, no preparation required
Use on Automated Chemistry Analyzers?	Yes	Yes
Test Principle	Diazo reaction with formation of an azobilirubin product, measured spectrophotometrically	Diazo reaction with formation of an azobilirubin product, measured spectrophotometrically
Calibration	Two points, blank (saline) and about 2.6 mg/dL total bilirubin	Two points, blank (saline) and about 2.6 mg/dL total bilirubin

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510(k) Summary, Continued

6) Comparison to predicate device (continued)

Feature	New Liquid Total Bilirubin Reagent	Predicate Total Bilirubin Reagent
Calibration Stability	Perform a new calibration once a week, or with a bottle or reagent lot change	Perform a new calibration once a week, or with a bottle or reagent lot change
Reagent On-board Stability	5 weeks	5 days
Kit Configuration, Reagent Preparation	R1, liquid, ready-to-use R2, liquid, ready-to-use	R1a, lyophilized, requires reconstitution with buffer R1, buffer

6) Comparison to predicate device, continued

Differences:

There are no significant differences between the Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin reagent and the predicate device for purposes of considering substantial equivalence.

Performance characteristics:

The performance of the Roche Diagnostics, Boehringer Mannheim Liquid Total Bilirubin reagent is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics, Boehringer Mannheim Total Bilirubin/DPD reagent system, catalog number 1039034, a modification of the Single Vial DPD Total Bilirubin reagent system, K781921.