K981883

JUL 7 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 28, 1998

2) Device name

Proprietary name: Roche Diagnostics, Boehringer Mannheim Liquid Direct 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 Direct Bilirubin reagent system, catalog number 704027, a modification of the Boehringer Mannheim / Hycel Bilirubin II reagent system, included in K790335.

4) Device Description

Direct bilirubin, in the absence 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 direct bilirubin concentration and can be measured photometrically.

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510(k) Summary, Continued

5) Intended use

The Roche Diagnostics, Boehringer Mannheim Liquid Direct Bilirubin reagent is intended for use for the quantitative determination of direct 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 Direct 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 Direct Bilirubin reagent system, catalog number 704027, a modification of the Boehringer Mannheim / Hycel Bilirubin II reagent system, included in K790335.

The following table illustrates the similarities between the Roche Diagnostics, Boehringer Mannheim Liquid Direct 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 Direct Bilirubin Reagent	Predicate Direct Bilirubin Reagent
Intended Use	Measurement of direct bilirubin	Measurement of direct 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	Uses commercially available calibrators with assigned values for direct bilirubin	Uses commercially available calibrators with assigned values for direct bilirubin

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6) Comparison to predicate device (continued)

Feature	New Liquid Direct Bilirubin Reagent	Predicate Direct Bilirubin Reagent
Calibration Stability	Perform a new calibration once a week, or with a bottle or reagent lot change	Perform a new calibration once daily, or with a bottle or reagent lot change
Reagent On-board Stability	4 weeks	14 days
Kit Configuration, Reagent Preparation	R1, liquid, ready-to-use R2, liquid, ready-to-use	R1, liquid, ready to use R2, combine bottles 2 (sulfanilic) and 2a (nitrite), then add 2b (diluent)

6) Comparison to predicate device, continued

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

Performance characteristics:
The performance of the Roche Diagnostics, Boehringer Mannheim Liquid Direct 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 Direct Bilirubin reagent system, catalog number 704027, a modification of the Boehringer Mannheim / Hycel Bilirubin II reagent system, included in K790335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 7 1998

Luann Ochs
Clinical Research Manager
Roche Diagnostics, Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Indiana 46256

Re: K981883
Liquid Direct Bilirubin Reagent
Regulatory Class: II
Product Code: CIG
Dated: May 28, 1998
Received: May 29, 1998

Dear Ms. Ochs:

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.

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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

Steven Gutman

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 Liquid Direct Bilirubin Reagent

Indications for Use:

The Roche Diagnostics, Boehringer Mannheim Liquid Direct Bilirubin reagent is intended for use for the quantitative determination of direct 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 _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off
Division of Clinical Laboratory Devices
510(k) Number k981883