K974733

510(k) Summary

JAN 26 1998

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

Boehringer Mannheim Corporation
9115 Hague Rd
Indianapolis, IN 46250
(317) 845-2386

Contact person: Ed Kimmelman

Date prepared: Dec. 17, 1997

2) Device name

Proprietary name: Boehringer Mannheim Direct LDL-Cholesterol

Common name: LDL test

Classification name: LDL and VLDL precipitation, cholesterol via esterase-oxidase, HDL

3) Predicate device

We claim substantial equivalence to the Equal Diagnostics LDL Direct Liquid Select™ Cholesterol Test.

4) Device description

The Boehringer Mannheim Direct LDL-Cholesterol test uses detergent and a sugar compound to inhibit reaction of VLDL, HDL and chylomicrons. The remaining LDL-Cholesterol is quantitatively measured with cholesterol esterase, cholesterol oxidase, and 4-aminoantipyrin.

5) Intended use

The Boehringer Mannheim Direct LDL-Cholesterol test is intended for the quantitative determination of low-density lipoprotein Cholesterol (LDL-C) in serum and plasma.

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6) Comparison to the predicate device

The Boehringer Mannheim Direct LDL-Cholesterol test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Equal Diagnostics LDL Direct Liquid Select™ Cholesterol Test.

The following table compares the Boehringer Manneheim Direct LDL-Cholesterol test with the predicate device. Specific data on the performance of the test have been incorporated into the draft labeling in Attachment 5. Labeling for the predicate device is provided in Attachment 6.

Similarities:

Feature	BM Direct LDL	Equal Direct LDL
Intended use	Same	Same
Sample type	Serum, plasma	Serum, plasma
Formulation	liquid reagents	liquid reagents
Instrument required	yes	yes
Inhibition approach	Uses detergent and a sugar compound to inhibit reaction of VLDL, HDL, and chylomicrons	Uses detergent to inhibit reaction of non-LDL lipoproteins
Measurement approach	Resulting cholesterol after inhibition is measured with cholesterol esterase, cholesterol oxidase, peroxidase, and 4-aminoantipyrin.	Resulting cholesterol after inhibition is measured with cholesterol esterase, cholesterol oxidase, peroxidase, and 4-aminoantipyrin.
Measuring range	3.0 - 550 mg/dL	6.6mg/dL - 992mg.dL

Differences: There are no significant differences between the BM Direct LDL and the predicate device for purposes of determining substantial equivalence.

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Summary, Continued

6) Comparison to predicate device (cont.)

Performance characteristics: The performance of the Boehringer Mannheim Direct LDL-Cholesterol method is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Equal Direct LDL system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 26 1998

Edward R. Kimmelman
Program Director, Regulatory Affairs and Compliance
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Indiana 46250

Re: K974733
Boehringer Mannheim Direct LDL Cholesterol
Regulatory Class: I
Product Code: LBR
Dated: December 15, 1997
Received: December 18, 1997

Dear Mr. Kimmelman:

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.

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 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): 974733

Device Name: Boehringer Mannheim Direct LDL - Cholesterol

Indications for Use: For the direct, quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum or plasma.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED)

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 974733