

510(k) Summary

JAN 22 1998 K974826

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- 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.
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- 1) Submitter name, address, contact** Boehringer Mannheim Corporation
9115 Hague Rd
Indianapolis, IN 46250
(317) 845-2386
- Contact person: Edward R. Kimmelman
- Date prepared: Dec. 23, 1997
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- 2) Device name** **Proprietary name:** Boehringer Mannheim Precipath® HDL/LDL-C
- Common name:** BM Precipath® HDL/LDL-C
- Classification name:** Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
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- 3) Predicate device** We claim substantial equivalence to the Sigma Diagnostics Cardiolid™ Controls. The intended use of the above controls is monitoring and control of processes for measuring the lipoproteins, HDL-C and LDL-C.
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- 4) Device description** The Boehringer Mannheim Precipath® HDL/LDL-C Control consists of lyophilized human serum with added HDL-Cholesterol and LDL-Cholesterol.
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- 5) Intended use** The Boehringer Mannheim Precipath® HDL/LDL-C Control is intended to be used in the monitoring and control of processes for measuring HDL-C and LDL-C.
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510(k) Summary, Continued

6) Comparison to the predicate device The Boehringer Mannheim Precipath® HDL/LDL-C control is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Sigma Diagnostics Cardiolidip™ Controls.

The intended use of this BM control and the predicate devices is the same in that they are intended to be used for the monitoring and control of test systems for the measurement of their labeled analytes.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 22 1998

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

Re: K974826
Precipath® HDL/LDL-C Control
Regulatory Class: I
Product Code: JJY, LBS
Dated: December 23, 1997
Received: December 24, 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.

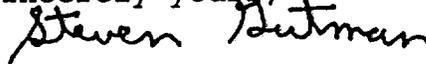
Page 2

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): K974826

Device Name: Boehringer Mannheim Precipath® HDL/LDL-C Control

Indications for Use: For the monitoring and control of processes for measuring the lipoproteins, HDL-C and LDL-C.

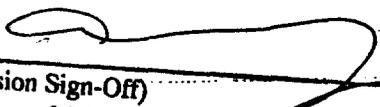
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use
(Optional format 1-2-96)


Division Sign-Off)
Division of Clinical Laboratory Device:

510(k) Number K974826