

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

Contact person: Priscilla A. Hamill

Date prepared: December 9, 1998

2) Device name **Proprietary name:** Preciset ® Serum Proteins

Common name: Preciset ® Serum Proteins

Classification name: Calibrator, Multi-analyte mixture

3) Predicate device We claim substantial equivalence to Preciset Serum Proteins calibrator, marketed by Boehringer Mannheim (K983469). The intended use of the above calibrators is the establishment of calibration curves for test systems for the quantitative determination of proteins in serum and plasma.

4) Device description The Preciset ® Serum Proteins consists of multi-level calibrators based on human serum. The concentrations of the components have been adjusted to ensure optimal calibration of the following immunoturbidimetric assays: Tina-quant ® IgA, Tina-quant ® IgG, Tina-quant ® IgM, Tina-quant ® C3, and Tina-quant ® C4, Transferrin, and C-Reactive Protein (CRP).

5) Intended use The Preciset ® Serum Proteins calibrator is intended to be used in the calibration of immunoturbidimetric assays on the BM/Hitachi systems.

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6) Comparison to the predicate device The Preciset ® Serum Proteins calibrator is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Boehringer Mannheim Preciset Serum Proteins.

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

Representative levels of constituent analytes The proposed product includes assayed values for constituent analytes. Representative levels are indicated in the table below.

**Representative Constituent Analyte Levels
Lot 698 922**

Constituent	Level 1	Level 2	Level 3	Level 4	Level 5	Units
IgG	194	408	845	1622	2985	mg/mL
IgA	50	94	193	400	723	mg/mL
IgM	28	51	103	213	388	mg/mL
C3	38	70	147	305	NA	mg/mL
C4	6.4	12.4	26.1	54.9	99.3	mg/mL
Transferrin	42	80	159	333	603	mg/mL
CRP	0.6	1.3	2.2	11.2	29.2	mg/mL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 20 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Priscilla A. Hamill
Regulatory Affairs Consultant
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Indiana 46250

Re: K984425
Trade Name: Preciset® Serum Proteins
Regulatory Class: II
Product Code: JIX
Dated: December 9, 1998
Received: December 11, 1998

Dear Ms. Hamill:

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 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). 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.

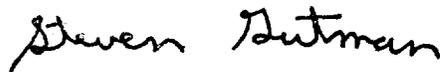
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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): K 984425

Device Name: Preciset ® Serum Proteins

Indications for Use: For calibration of immunoturbidimetric assays on BM/Hitachi systems

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 984425

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

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)