

174 1000
OCT - 7 1997

**BOEHRINGER
MANNHEIM
CORPORATION** 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
4300 Hacienda Drive
Pleasanton, CA. 94588-2722
(510) 730-8413

Contact Person: Yvette Lloyd

Date Prepared: September 19, 1997

2. Device Name Proprietary name: Precinorm and Precipath® RF Controls
Common name: Controls
Classification name: Single (specified) analyte controls (assayed + unassayed)

3. Predicate device The Boehringer Mannheim Precinorm and Precipath® RF Controls are a new product.

The Boehringer Mannheim Precinorm and Precipath® RF Controls are substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the Behring N/T Rheumatology Control SL1, SL2 (K962373).

4. Device Description The Boehringer Mannheim Precinorm and Precipath® RF Controls are manufactured using human serum albumin, Rheumatoid Factor, and stabilizers. The analyte is appropriately spiked into the control matrix to the correct control concentration levels. The controls are in process checked, and a value assignment process is done via a comparison to an analyte specific (and chemistry specific) calibrator.

Continued on next page



5.
Intended use

The Boehringer Mannheim Precinorm and Precipath® RF Controls are used for the quality control of the Boehringer Mannheim Tinaquant RF assay.

6.
Comparison
to predicate
device

The Boehringer Mannheim Precinorm and Precipath® RF Controls are substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the Behring N/T Rheumatology Control SL1, SL2 (K962373).

The following table compares the Boehringer Mannheim Precinorm® TDM Controls with the predicate device, the Behring N/T Rheumatology Control SL1, SL2. Specific data on the performance of the controls have been incorporated into the draft labeling in attachment 5. Labeling for the predicate devices are provided in attachment 6..

Similarities:

- Similar intended use
- Similar matrix

Continued on next page



Differences:

Feature	Precinorm/Precipath ® RF Control	Behring N/T Rheumatology Control SL1/SL2
Analytes	Rheumatoid Factor	Rheumatoid Factor, ASL, CRP
Reconstitution Instructions	Add 1 mL of distilled water, then let dissolve with occasional swirling.	Ready for use (liquid stable)

**6. Comparison
to predicate
device, (cont.)**

Performance Characteristics:

- Dose assignment and stability: equivalent performance to the predicate device.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 7 1997

Ms. Yvette Lloyd
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
4300 Hacienda Drive
Pleasanton, California 94588-2722

Re: K973629
Trade Name: Precinorm and Precipath® RF Controls
Regulatory Class: I
Product Code: JJY
Dated: September 22, 1997
Received: September 24, 1997

Dear Ms. Lloyd:

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 requirement, 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.

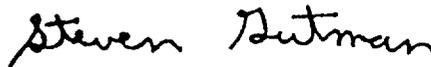
Page 2

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 at (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): 15973601

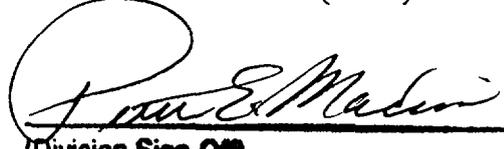
Device Name: Precinorm & Precipath RF Controls

Indications For Use:

The Precinorm and Precipath® RF Controls are used for the quality control of the Boehringer Mannheim Tinaquant Rheumatoid Factor assay.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)