

510(k) Summary

DE 11-3-1997

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- 8215
Fax number: (510)-225-0654

Contact Person: Patricia M. Klimley

Date Prepared: November 14, 1997

2. Device Name Proprietary name: Elecsys® CalCheck™ Vitamin B12
Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed + unassayed)

3. Predicate device The Boehringer Mannheim Elecsys® CalCheck™ Vitamin B12 is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH Calibration Verification Test (K963147).

4. Device Description The Boehringer Mannheim Elecsys® CalCheck™ Vitamin B12 is manufactured using human serum albumin, vitamin B12, stabilizers, and preservatives. The analyte is appropriately spiked into the calcheck matrix to the correct calcheck concentration levels. The calcheck are in process checked and quality controlled against in-house standards.

Continued on next page

510(k) Summary, Continued

5. Intended use The Boehringer Mannheim Elecsys® CalCheck™ Vitamin B12 is used to verify the calibration assignment for the Boehringer Mannheim Elecsys Vitamin B12 assay.

6. Comparison to predicate device The Boehringer Mannheim Elecsys® CalCheck™ Vitamin B12 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH Calibration Verification Test (K963147).

Both products are intended to be used for the verification of calibration for analytes on automated immunoassay analyzers.

The following table compares the Elecsys® CalCheck™ Vitamin B12 with the predicate device, Elecsys® CalCheck™ TSH. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate devices are provided in attachment 6.

Similarities:

- Configuration: 3 CalCheck levels: low, mid, and high
- Intended use: To verify calibration

Differences:

Feature	CalCheck Vitamin B12	CalCheck TSH
Matrix type	Human serum albumin	Horse serum
Analyte	Vitamin B12	TSH

7. Performance Characteristics The Elecsys® CalCheck™ Vitamin B12 was evaluated for value assignment and stability.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 8 1997

Patricia M. Klimley
Regulatory Affairs Manager
Boehringer Mannheim Corporation
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, California 94566-0900

Re: K974383
Elecsys® CalCheck™ Vitamin B12
Product Code: JJX
Regulatory Class: I
Dated: November 20, 1997
Received: November 21, 1997

Dear Ms. Klimley:

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 (Pre-market 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 pre-market 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.

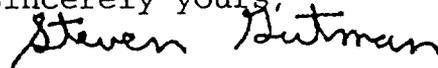
Page 2

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): N/A **K 974383**

Device Name: Boehringer Mannheim Elecsys® CalCheck™ Vitamin B12

Indications For Use:

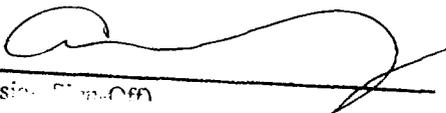
Elecsys CalCheck Vitamin B12 calibration verification solutions comprise three levels - low, mid, and high - each with a defined Vitamin B12 concentration. The low solution concentration is near the clinical deficiency range of the assay. The mid solution is in the middle point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys CalCheck Vitamin B12 is intended for use in periodic verification of the calibration of the Elecsys Vitamin B12 assay.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF 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 Chief/Off)
Division of Regulatory Devices
510(k) number K 974383