

11413473  
NOV 5 1997

## 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  
4300 Hacienda Drive  
Pleasanton, CA 94588-2722  
(510) 730 - 8415  
Fax number: (510) 225 - 0654

Contact Person: Jody J. Savage

Date Prepared: October 17, 1997

---

**2. Device Name**

Proprietary name: Elecsys® CalCheck™ DIGOXIN

Common name: Calibration Verification Material

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

---

**3. Predicate device**

The Elecsys® CalCheck™ DIGOXIN is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH (K963147).

---

**4. Device Description**

The Elecsys® CalCheck™ DIGOXIN is a three level single analyte set of stable liquid, bovine based materials. They are assayed in triplicate and the results compared to the target values.

---

*Continued on next page*

## 510(k) Summary, Continued

---

**5. Intended use** The Boehringer Mannheim Elecsys CalCheck DIGOXIN is used to verify the calibration assignment for the Boehringer Mannheim Elecsys DIGOXIN assay.

---

**6. Comparison to predicate device** The Elecsys® CalCheck™ DIGOXIN is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH (K963147).

The following table compares the Elecsys® CalCheck™ DIGOXIN with the predicate devices, 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 is provided in attachment 6.

### Similarities:

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

### Differences:

| Feature     | CalCheck DIGOXIN | CalCheck TSH |
|-------------|------------------|--------------|
| Matrix type | Bovine serum     | Horse serum  |
| Analyte     | DIGOXIN          | TSH          |

---

*Continued on next page*



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Jody J. Savage  
Consultant, Regulatory Affairs  
Boehringer Mannheim  
4300 Hacienda Drive  
Pleasanton, California 94588-2722

NOV - 4 1997

Re: K973973  
Elecsys® CalCheck™ DIGOXIN  
Regulatory Class: I  
Product Code: DMP  
Dated: October 17, 1997  
Received: October 20, 1997

Dear Ms. Savage:

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.

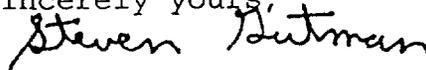
Page 2

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): N/A

Device Name: Elecsys® CalCheck™ DIGOXIN

Indications For Use:

Elecsys® CalCheck™ DIGOXIN calibration verification solutions comprise three levels - low, mid, and high - each with a defined DIGOXIN concentration. The low solution concentration is near the lower detection limit of the assay. The mid solution is in the middle or at the clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys® CalCheck™ DIGOXIN is intended for use in periodic verification of the calibration of the Elecsys® DIGOXIN reagent.

(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 KG73973

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)