K020883

# 510(k) Summary

NOV 2 9 2002

**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.

**Submitter name, address, contact**

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
521 - 3831

Contact Person: Sherri L Coenen

Date Prepared: March 15, 2002

**Device Name**

Proprietary name: Elecsys® proBNP CalCheck

Common name: Calibration Verification Material

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

**Predicate device**

The Elecsys® proBNP CalCheck is substantially equivalent to the currently marketed Elecsys® Thyroglobulin CalCheck (K001015).

**Device Description**

The Elecsys® proBNP CalCheck is a lyophilized product manufactured using proBNP in human serum matrix. The analyte is appropriately spiked into the CalCheck matrix to the correct concentration levels.

## 510(k) Summary, Continued

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|---|---|
| **Intended use** | The Elecsys® proBNP CalCheck is used in the verification of the calibration established by the Elecsys® proBNP reagent on Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers. |
| **Comparison to predicate device** | The Elecsys® proBNP CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® Thyroglobulin CalCheck (K001015). |
| **Performance Characteristics** | The Elecsys® proBNP CalCheck was evaluated for value assignment and stability. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor
Regulatory Program Principal
Centralized Diagnostic Submissions
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

NOV 2 9 2002

Re: k020883
Trade/Device Name: Elecsys® proBNP CalCheck
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: November 20, 2002
Received: November 22, 2002

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if known): N/A

Device Name: Elecsys® proBNP CalCheck

Indications For Use:

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

The Elecsys® proBNP CalCheck is intended for use in the verification of the calibration established by the Elecsys® proBNP reagent on Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 620883