

K902571

510(k) Summary

APR 22 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.

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2) Device name **Proprietary name: CoaguChek™ PST System**

Common name: prothrombin time test

3) Predicate device We claim substantial equivalence to **Boehringer Mannheim's CoaguChek™ System.**

4) Device Description • The CoaguChek test strip contains reagent and iron particles. Blood mixes with these reagents and particles on the test strip. At the same time, the meter starts a timer. The iron particles move in response to an oscillating magnetic field. When the blood clots, the particles stop moving. The meter stops the timer and displays the result.

Continued on next page

Boehringer Mannheim Corporation

CoaguChek® PST System
510(k) Premarket Notification

510(k) Summary, Continued

5) Intended use For quantitative prothrombin time (PT) testing in fresh capillary blood with the CoaguChek System by properly selected and suitably trained patients (or their care givers) on the prescription of the treating doctor.

6) Comparison to predicate device The Boehringer Mannheim CoaguChek PST System 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 CoaguChek System. The following tables compare the CoaguChek PST with the predicate device.

A study was conducted comparing test results obtained by trained patients with those obtained by health care professionals, when both were using the CoaguChek PST System. The correlation was very good, as indicated by the following statistics: N = 315 observations, Slope = 0.973, Intercept = 0.05, and Correlation Coefficient = 0.966. This study shows that trained patients are able to obtain results that are as accurate as those obtained by health care professionals trained in the use of the CoaguChek System.

In a previous Premarket Notification (#k930454) Boehringer Mannheim demonstrated the CoaguChek System was compared against Boehringer Mannheim's CoaguChek Plus System and the MLA 700 Analyzer. In August, 1993, FDA determined the CoaguChek System was substantially equivalent to those test systems.

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510(k) Summary, Cont'd**SIMILARITIES**

| Feature | CoaguChek System (the Predicate Device) | CoaguChek PST System (the New Device) |
|------------------------------------|--|--|
| Principle of Operation | The CoaguChek test strip contains reagent and iron particles. Blood mixes with these reagents and particles on the test strip. At the same time, the meter starts a timer. The iron particles move in response to an oscillating magnetic field. When the blood clots, the particles stop moving. The meter stops the timer and displays the result. | Same. Principle of operation is not effected by introduction of new user group. |
| Meter Calibration Procedure | Test strip package insert and Meter User's Manual instruct the user to change the Code Chip with each new package of test strips. | Same. A Code Chip is provided in each package of test strips. The meter calibration procedure is not effected by introduction of new user group. |
| Meter Cleaning | Meter User's Manual describes the cleaning procedure which consists of wiping strip guide and other surfaces with a cloth dampened with 10% household bleach solution. | Same. Meter cleaning procedure is not effected by introduction of new user group. |
| Hematocrit Range | Hematocrit ranges between 32-52% do not significantly affect test results. | Same. Test strip and meter design were not effected by the proposed modification (i.e., new user group). |
| Fail-Safe Mechanisms | Fail-safe mechanisms built into meter and error code messages were described in 510(k) file #k930454. | Same. The meter was initially designed for use by patients so no redesign was required. |

510(k) Summary, Cont'd**SIMILARITIES, Cont'd**

| Feature | CoaguChek System (the Predicate Device) | CoaguChek PST System (the New Device) |
|---|--|--|
| Storage and Operating Condition Limits | <p>Test Strips & Liquid Controls: Store strips and liquid controls in refrigerator at +35°F to +45°F until ready to use. Do not freeze. Test strips are stable for 60 days or the expiration date, whichever comes first, when stored at room temperature (below 86°F). Remove test strip foil pouch and control vial from refrigerator for at least five minutes before performing test. The strip pouch and control vial should be at room temperature (65°F - 90°F) before opening.</p> <p>Meter: 65°F - 90°F, 10-85% relative humidity (without condensation).</p> | Same. The recommended storage and operating conditions are not effected by the introduction of the new user group. |
| Measuring Range | The CoaguChek system has a PT measuring range of 9.6 to 36.9 seconds (NAS) and 0.64 to 9.5 INR. | Same. |
| Sensitivity | The CoaguChek System is sensitive to deficiencies of Factor II, V, VII, and X. | Same. |
| Meter Size | 2.2 x 5.5 x 8.8 inches 1.5 lb. | Same. |
| Meter Memory | 30 tests with time and date | Same. |

510(k) Summary, Cont'd**DIFFERENCES**

| Feature | CoaguChek System (the Predicate Device) | CoaguChek PST System (the New Device) |
|---|--|--|
| Recommended Quality Control Strategy | Health care professionals are directed to perform daily control testing as required by CLIA '88. A two-level Electronic Quality Control cartridge is available from Boehringer Mannheim as well as two liquid controls to meet the regulatory requirements. | Two levels of control should be tested upon receipt of each test strip carton and each day of use. |
| User Environment and Qualifications | Cleared for use by health care professionals, including Home Health Care nurses, within operating conditions specified in User's manual. As noted on previous page, the recommended storage and operating conditions are not effected by the introduction of the new user group. | Intended for use by health care professionals and properly selected and suitable trained patients within operating conditions specified in device labeling. |

510(k) Summary, Cont'd

DIFFERENCES, Cont'd

| Feature | CoaguChek System (the Predicate Device) | CoaguChek PST System (the New Device) |
|-----------------------------|---|--|
| Test System Labeling | 510(k) cleared labeling intended for health care professional. Labeling for predicate device is provided in attachment 8. | <p>Labeling content intended for patient rewritten to 7th grade reading level or lower.</p> <p>Additional labeling created to assist professionals with suitable selection and proper training of patients.</p> <p>Labeling for proposed test kit is provided in attachment 7.</p> |
| Specimen Collection | Test procedure is described in the package insert and the Meter User's Manual. The labeling describes dosing test strips with either fresh capillary or venous blood samples. | Patient is limited to testing only fresh capillary whole blood samples. All other aspects of test procedure (e.g., strip insertion into meter before dosing strip) are not effected by introduction of new user group. |