MAY 2 4 2004

K040296

8.0 Premarket Notification 510(k) Summary

[As required by section 807.92(c)]

Applicant:	Michael J. Morris R2 Diagnostics, Inc. 412 South Lafayette Blvd. South Bend, IN 46601 USA
Contact:	Dr. Peggy S. Carter R2 Diagnostics, Inc. 412 South Lafayette Blvd. South Bend, IN 46601 TEL: (574) 288-4377 FAX: (574) 288-2272
Date:	December 19, 2003
Trade Name:	R2 Diagnostics Phosphoplastin RL
Common Name:	Prothrombin Time
Classification Name:	Test, Time, Prothrombin (per 21 CFR section 864.7750)
Comparison Device:	Phosphoplastin R, K940082

Description of the Device and Intended Use

Phosphoplastin RL PT reagent is a liquid, ready-to-use reagent containing thromboplastin derived from rabbit brain, calcium ions, buffers, stabilizers and preservatives. Phosphoplastin RL is intended for use in a one-stage prothrombin time (PT) test on citrated human plasma. The PT test is a quantitative assay used in the general patient population for routine screening to detect deficiencies in the extrinsic pathway of coagulation. The PT test is also used to monitor oral anticoagulant therapy and should be used in a clinical laboratory by qualified laboratory personnel.

Summary of Substantial Equivalence Comparisons

R2 Diagnostics Phosphoplastin RL is substantially equivalent in intended use and performance to Phosphoplastin R. Both the predicate device and the proposed product are formulated to detect deficiencies in factors II, V, VII, and X (PT and PT-based factor assays). Both reagents are also sensitive to oral anticoagulants. In correlation studies normal and abnormal patient plasma, as well as plasma samples from patients undergoing oral anticoagulant therapy, were tested using both reagents. Comparison of INR data from PT testing at two sites and on two different instrument types yielded correlation coefficients of $r^2 = 0.986$ (photo-optical), slope = 0.882 and $r^2 = 0.915$ (mechanical), slope = 1.162. Within-run and between-run precision studies were also performed and CV's of less than 3% were obtained for the proposed device. CV's of less than 3% are also reported for the predicate device in the manufacturers directional insert.

Conclusion: Substantial Equivalence Statement

In Summary, the identical intended use, similar technological characteristics and the performance data provided in this premarket notification demonstrate that R2 Phosphoplastin RL is substantially equivalent to Phosphoplastin R.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 4 2004

Peggy Carter, Ph.D.
Director, Product Development
R2 Diagnostics
412 S. Lafayette Boulevard
South Bend, Indiana 46601

Re: k040296
Trade/Device Name: Phosphoplastin RL
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: II
Product Code: GJS
Dated: May 4, 2004
Received: May 5, 2004

Dear Dr. Carter:

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). You may obtain other general information on your responsibilities under the Act 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,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

6.0 Indications for Use

510(k) Number (if known)K040296

Device Name: Phosphoplastin RL

Indications for Use:

Statement of Indications for Use

The Phosphoplastin RL Prothrombin Time reagent is a liquid PT reagent containing thromboplastin derived from rabbit brain and calcium ions for use in the determination of Prothrombin Time (PT) and related coagulation procedures. The PT test is a one-stage quantitative test performed on plasma samples in the general patient population. The PT test is used in routine patient screening for disorders in the extrinsic pathway of coagulation and for the monitoring of patients undergoing Oral Anti-Coagulant (OAC) therapy. Phosphoplastin RL should only be used in an appropriate clinical laboratory by qualified laboratory personnel and is provided ready-to-use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040296