K033612

DEC 18 2003

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.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 2386

Contact Person: Robert A. Gregg

Date Prepared: November 14, 2003

Device Name

Proprietary name: Factor II (Prothrombin) G20210A Kit

Common name: Factor II (Prothrombin) G20210A Kit

Classification name: Factor deficiency test

Device Description

The Factor II (Prothrombin) G20210A Kit is an in vitro diagnostic test for the detection and genotyping of the Factor II (Prothrombin) G20210A mutation, from DNA isolated from human whole peripheral blood.

Intended use

The Factor II (Prothrombin) G20210A Kit allows the detection and genotyping of a single point mutation (G to A at position 20210) of the human Factor II gene, from DNA isolated from human whole peripheral blood. The test is performed on the LightCycler Instrument utilizing polymerase chain reaction (PCR) for the amplification of Factor II DNA recovered from clinical samples and fluorigenic target-specific hybridization for the detection and genotyping of the amplified Factor II DNA.

The test is intended to be used on the LightCycler using SW 3.5. The sample preparation must be performed according to the workflow procedure described in the package insert.

Indications for Use

The Factor II (Prothrombin) G20210A Kit is is an *in vitro* diagnostic test for the detection and genotyping of the Factor II (Prothrombin) G20210A mutation as an aid to diagnosis in the evaluation of patients with suspected thrombophilia.

Substantial equivalence

The Factor II (Prothrombin) G20210A Kit gives equivalent results to a DNA sequencing method. A total of 572 samples were tested and 99.5% agreement was observed between the methods.

Performance characteristics

The following table lists performance characteristics of the Factor II (Prothrombin) G20210A Kit

Table 2 - Performance Characteristics

Feature	Factor II (Prothrombin) G20210A Kit performance
Precision	Within-run • T_m1: 0.14 – 0.26 % CV • T_m2: 0.14 – 0.24 % CV • ΔT_m: 0.58- 0.90% CV Total • T_m1: 0.19 – 0.33 % CV • T_m2: 0.22 – 0.44 % CV • ΔT_m: 1.23- 1.53 % CV Overall median: 0.36%
Analytical sensitivity (LDL)	< 50 allele copies per reaction
Reagent Stability	• Store up to stated expiration date at -15 to -25°C. • Protect from light • Freeze immediately after use • Kit reagents may be frozen and thawed up to five times
Interferences	High concentrations of heparin might interfere with the polymerase chain reaction. No interference from EDTA or citrate anticoagulants.
Precautions and Warnings	• One rare mutation will lead to false-positive result after performing the melting curve analysis (*i.e.*, the mutation A20218G)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2003

Robert Gregg, Ph.D.
Director, Regulatory Submissions
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250

Re: k033612
Trade/Device Name: Factor II (prothrombin) G20210A Kit
Regulation Number: 21 CFR 864.7280
Regulation Name: Factor V Leiden DNA mutation detection systems
Regulatory Class: Class II
Product Code: NPR
Dated: November 14, 2003
Received: November 17, 2003

Dear Dr. Gregg:

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 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~~ K033612

Device Name:

Factor II (Prothrombin) G20210A Kit

Indications For Use:
The Factor II (Prothrombin) G20210A Kit is an *in vitro* diagnostic test for the detection and genotyping of a single point mutation (G to A at position 20210) of the human Factor II gene, from DNA isolated from human whole peripheral blood.

The Factor II (Prothrombin) G20210A Kit is indicated as an aid to diagnosis in the evaluation of patients with suspected thrombophilia.

The test is intended to be used on the LightCycler Instrument. The sample preparation must be performed according to a workflow procedure described in the package insert.

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

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033612