K990992

SEP 30 1999

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 Rd
Indianapolis, IN 46250
(317) 576-3723

Contact person: Priscilla A. Hamill

Date prepared: September 28, 1999

Device name

Proprietary name: INTEGRA Reagent Cassette for Hemoglobin A1c

Common name: Hemoglobin A1c

Classification name: Glycosylated Hemoglobin Assay

Predicate device

The INTEGRA Reagent Cassette for Hemoglobin A1c is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Roche INTEGRA Reagent Cassette for Hemoglobin A1c (K961824)

Device description

The device is an immunoturbidimetric test for the quantitative determination of per cent Hemoglobin A1c in anticoagulated venous or capillary whole blood for use on the INTEGRA family of analyzers.

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510(k) Summary, Continued

Intended use	For in vitro quantitative determination Hemoglobin A1c in anticoagulated whole blood.
Substantial equivalence – similarities	The INTEGRA Reagent Cassette for Hemoglobin A1c is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Roche INTEGRA Reagent Cassette for Hemoglobin A1c (K961824). The following table illustrates the similarities between the modified INTEGRA Reagent Cassette for Hemoglobin A1c and the predicate device. Draft labeling is included in Section V of this submission. Labeling for the predicate device is provided in Section VI.

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Feature	Modified Device (Roche INTEGRA Cassette for Hemoglobin A1c Whole Blood Application)	Modified Device (Roche INTEGRA Cassette for Hemoglobin A1c Hemolysate Application)
Intended use	For the quantitative determination of Hemoglobin A1c.	For the quantitative determination of Hemoglobin A1c.
Indications for use	For monitoring of long term blood glucose control in individuals with diabetes mellitus.	For monitoring of long term blood glucose control in individuals with diabetes mellitus.
Methodology	• Immunoturbidimetric test for HbA1c • Colorimetric test for Total Hb	• Immunoturbidimetric test for HbA1c • Colorimetric test for Total Hb
Measure-ment approach	Spectrophotometric	Spectrophotometric
Instrument required	INTEGRA family of analyzers	INTEGRA family of analyzers
Measuring range	• Hb: 81-644 mg/dL • HbA1c: range depends on value of HbA1c calibrator; a typical range is 1.3-41.9 mg/dL • For a typical value of Hb of 13.2 g/dL, the test range for the final HbA1c(%) results is 3-31%	• Hb: 81-644 mg/dL • HbA1c: range depends on value of HbA1c calibrator; a typical range is 1.3-41.9 mg/dL • For a typical value of Hb of 13.2 g/dL, the test range for the final HbA1c(%) results is 3-31%
Sample type	Anticoagulated venous or capillary blood	Anticoagulated venous or capillary blood

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Substantial equivalence -- differences

The primary difference between the modified device and the predicate device is that the preparation of hemolysate is automated on the INTEGRA analyzer. Minor modifications in formulation and application parameters have also been made.

The following table illustrates the differences between the INTEGRA Reagent Cassette for Hemoglobin A1c and the predicate device.

Feature	Modified Device (Roche INTEGRA Cassette for Hemoglobin A1c Whole Blood Application)	Modified Device (Roche INTEGRA Cassette for Hemoglobin A1c Hemolysate Application)
Sample preparation	Automated preparation of hemolysate from anticoagulated venous or capillary blood	Manual preparation of hemolysate from anticoagulated venous or capillary blood
Reagent Formulation	Modification in component concentrations.	• Latex coated with mouse MAB for HbA1c • Buffer, pH 11.5 • BSA • Formate • Agglutinator
Hemolyzing reagent	• 80 mmol/L citric acid • pepsin >1500 kU/L	• 20 mmol/L citric acid • pepsin >100kU/L
Wavelength	• Hb – 552/659 • HbA1c - 552 nm	• Hb – 552/659 • HbA1c - 552 nm

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Substantial equivalence -- performance characteristics

Performance characteristics of the two devices are equivalent.

Feature	Modified Device (Roche INTEGRA Cassette for Hemoglobin A1c Whole Blood Application)	Modified Device (Roche INTEGRA Cassette for Hemoglobin A1c Hemolysate Application)
Precision	Within-run CV 2.3% at 4.7% 2.2% at 10.3% Total CV 2.4% at 4.7% 2.4% at 10.3%	Within-run CV 1.5% at 4.8% 1.8% at 12.1% Total CV 2.8% at 4.8% 2.4% at 12.1%
Analytical sensitivity	Hb: 1.5 mg/dL HbA1c: 0.4 mg/dL	Hb: 1.5 mg/dL HbA1c: 0.4 mg/dL
Interfering substances	No significant interference from unconjugated bilirubin (60 mg/dL), lipemia (2000 mg/dL), or glycemia (1000 mg/dL), acetylated Hb, carbamylated Hb, and labile HbA1c.	No significant interference from icterus (25 mg/dL), lipemia (2000 mg/dL), or glycemia (1000 mg/dL), acetylated Hb, carbamylated Hb, and labile HbA1c.
Calibration stability	Each lot and every 57 days	Each lot and every 43 days

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 30 1999

Ms. Priscilla Hamill
Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K990992
Trade Name: INTEGRA Reagent Cassette for Hemoglobin A1c
Regulatory Class: II
Product Code: LCP
Dated: July 30, 1999
Received: August 2, 1999

Dear Ms. Hamill:

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 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). 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.

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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

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): K990992

Device Name: INTEGRA Reagent Cassette for Hemoglobin A1c

Indications for Use:

For the quantitative determination of Hemoglobin A1c in anticoagulated whole blood.

Hemoglobin A1c is indicated for the monitoring of long term blood glucose control in individuals with diabetes mellitus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Peter E Maheu

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990992