

APR 14 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: February 23, 1999

Device name **Proprietary name:** INTEGRA Reagent Cassette for Apolipoprotein B
Common name: Apolipoprotein B
Classification name: Lipoprotein Test System

Predicate device We claim substantial equivalence to the currently marketed Roche INTEGRA Reagent Cassette for Apolipoprotein B.

Device description The device is an immunoturbidimetric test for the quantitative determination of Apolipoprotein B in serum and plasma for use on the INTEGRA family of analyzers.

510(k) Summary, Continued

Intended use	For in vitro quantitative determination of Apolipoprotein B in serum and plasma
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Substantial equivalence – similarities	The INTEGRA Reagent Cassette for Apolipoprotein B 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 Apolipoprotein B (K951595)
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The following table illustrates the similarities between the modified INTEGRA Reagent Cassette for Apolipoprotein B and the predicate device. Specific data on the performance of the test have been incorporated into the draft labeling in Section V of this submission. Labeling for the predicate device is provided in Section VI.

Continued on next page

510(k) Summary, Continued

Feature	Modified Device	Predicate Device
Intended use	For the quantitative determination of Apolipoprotein B.	For the quantitative determination of Apolipoprotein B.
Indications for use	Apolipoprotein B measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.	Apolipoprotein B measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
Methodology	Immunoturbidimetric	Immunoturbidimetric
Measure-ment approach	Spectrophotometric	Spectrophotometric
Instrument required	INTEGRA family of analyzers	INTEGRA family of analyzers
Measuring range	0.26-3.9 g/L 0.09-7.8 g/L with rerun	0.26-3.9 g/L 0.09-7.8 g/L with rerun
Formulation	Anti-apolipoprotein B T antiserum (sheep) specific for human apolipoprotein B in phosphate buffer stabilized with 0.09% sodium azide.	Anti-apolipoprotein B T antiserum (sheep) specific for human apolipoprotein B in phosphate buffer stabilized with 0.09% sodium azide.

Substantial equivalence -- differences

The modified device differs from the predicate device in that plasma is now claimed as an acceptable specimen type.

The following table illustrates the differences between the INTEGRA Reagent Cassette for Apolipoprotein B and the predicate device.

Feature	Modified Device	Predicate Device
Sample type	Serum and plasma	Serum

Substantial equivalence -- performance characteristics

Performance characteristics, including precision, analytical sensitivity, calibration interval, and limitations statements for the two devices are equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 14 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Priscilla A. Hamill
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, Indiana 46250-0457

Re: K990595
Trade Name: INTEGRA Reagent Cassette for Apolipoprotein B
Regulatory Class: II
Product Code: DFC
Dated: February 23, 1999
Received: February 24, 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.

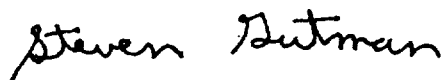
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

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): K 990595

Device Name: INTEGRA Reagent Cassette for Apolipoprotein B

Indications for Use:

For the quantitative determination of apolipoprotein B in serum and plasma.

A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.

Jean Conner
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 990595

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐
(Optional format 1-2-96)