K122722

NOV 29 2012

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System

Purpose

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

The purpose of this premarket notification is to obtain FDA review and clearance for the **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay, Preciset Lp(a) Gen.2 calibrator set, and PreciControl Lp(a) Gen.2 control set.

Device name

Proprietary name: (1) **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay
(2) Preciset Lp(a) Gen.2 calibrator set
(3) PreciControl Lp(a) Gen.2 control set

Common name: (1) TQ Lp(a) Gen.2
(2) Preciset Lp(a) Gen.2 calibrator set
(3) PreciControl Lp(a) Gen.2 control set

Classification: (1) Low-Density Lipoprotein Immunological Test System
(2) Calibrator, secondary
(3) Single (specified) analyte controls (assayed and unassayed)

Establishment registration

For the **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay, Preciset Lp(a) Gen.2 calibrator set, and PreciControl Lp(a) Gen.2 control set, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126. The establishment registration number for Roche Diagnostics United States is 1823260.

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Classification

The FDA has classified the Low-Density Lipoprotein Immunological Test System (TQ Lp(a) Gen.2) and the calibrator (Preciset Lp(a)) as Class II devices.
The FDA has classified the single (specified) analyte controls (assayed and unassayed) (PreciControl Lp(a)) as a Class 1 (reserved) device.

Panel	Product Code	Classification Name	Regulation
Clinical Chemistry	DFC	Low-Density Lipoprotein Immunological Test System	21 CFR 866.5600
Clinical Chemistry	JIT	Calibrator, secondary	21 CFR 862.1150
Clinical Chemistry	JJX	Single (specified) analyte controls (assayed and unassayed)	21 CFR 862.1660

Performance standards

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Proposed labeling

Draft labeling sufficient to describe the device, its intended use, and the directions for use on the **cobas c** 501 analyzer is attached. We believe the draft version of the device labeling presented in Section 8 contains all of the technical information required per 21 CFR 809.10 for the **cobas c** Tina-quant Lipoprotein (a) Gen.2 test system.

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Device description

The TQ Lp(a) Gen.2 test principle is a particle-enhanced immunoturbidimetric assay. Human lipoprotein (a) agglutinates with latex particles coated with anti-Lp(a) antibodies. The precipitate is determined turbidimetrically.

The Preciset Lp(a) Gen.2 calibrator set consists of five lyophilized calibrators based on a stabilized and lyophilized pool of human plasma. The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

The PreciControl Lp(a) Gen.2 control set contains two lyophilized controls based on a human plasma matrix.

Intended use/indications for use

cobas c Tina-quant Lipoprotein (a) Gen.2 assay:
The **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay is an in vitro test intended for the quantitative determination of lipoprotein(a) [Lp(a)] in human serum and plasma the Roche/Hitachi **cobas c** 501 analyzer. The measurement of Lp(a) is useful in evaluation of lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation and other lipoprotein tests.

Preciset Lp(a) Gen.2 calibrator set:
The Preciset Lp(a) Gen.2 calibrator set is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

PreciControl Lp(a) Gen.2 control set:
The PreciControl Lp(a) Gen.2 control set is intended for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Substantial equivalence

The **cobas c** Tina-quant Lipoprotein (a) Gen.2 Test System is substantially equivalent to other devices legally marketed in the United States.

(1) **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay is equivalent to Lp(a)-Latex SEIKEN assay, Denka Seiken Co., Ltd. (k013359).

(2) Preciset Lp(a) Gen.2 calibrator set is equivalent to the Diazyme Lp(a) calibrator set, General Atomics (k082488).

(3) PreciControl Lp(a) Gen.2 control set is equivalent to the Diazyme Lp(a) control set, General Atomics (k082488).

Substantial equivalence - comparison

The following tables compare the **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay, Preciset Lp(a) Gen.2 calibrator set, and PreciControl Lp(a) Gen.2 control set with their respective predicate devices.

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Comparison of assays – similarities and differences

Assay Comparison		
Feature	**Lp(a)-Latex Seiken assay (predicate device: k013359)**	**TQ Lp(a) Gen.2 assay (candidate device)**
Intended Use/Indications for Use	The Lp(a)-Latex Seiken Assay kit is an in vitro diagnostic test for the quantitative determination of lipoprotein(a) [Lp(a)] in huma serum and plasma samples using Hitachi 917 analyzer. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation and other lipoprotein tests.	The **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay is an in vitro test intended for the quantitative determination of lipoprotein(a) [Lp(a)] in human serum and plasma the Roche/Hitachi **cobas c** 501 analyzer. The measurement of Lp(a) is useful in evaluation of lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation and other lipoprotein tests.
Assay principle	immunoturbidimetric	same
Sample types	Human serum and Na_2-EDTA, K_2-EDTA, Na-heparin, Li-Heparin, and Citric acid plasma	Human serum and K_2-EDTA, K_3-EDTA, and Li-Heparin
Instrument Platform	Roche/Hitachi 917 analzyer	**cobas c** 501 analyzer
Calibrator	Lp(a)-Latex Seiken Assay Kit Calibrators	Preciset Lp(a) Gen.2 calibrator set
Calibration Frequency	After reagent lot change and as required following quality control procedures.	same
Calibration mode	Six point; spline	same
Controls	commercially available controls	PreciControl Lp(a) control set (2 levels)
Reagent active ingredients	R1: glycine buffer solution R2: latex particles with anti-Lp(a) antibodies	R1: glycine buffer solution R3: latex particles with anti-Lp(a) antibodies

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Comparison of assays – similarities and differences

(continued)

Assay Comparison		
Feature	**Lp(a)-Latex Seiken assay (predicate device: k013359)**	**TQ Lp(a) Gen.2 assay (candidate device)**
Reagent Stability	Unopened: 2-10°C until expiration date On-board in use: N/A	Unopened: 2-8°C until expiration date On-board in use: 6 weeks
Measuring range	2.0 – 80.0 mg/dL	6.0 – 80.0 mg/dL
Lower Limits of Measure	LDL: 2.0 mg/dL LoB, LoD, and LoQ not tested	LDL: not tested LoB: 3 mg/dL LoD: 4 mg/dL LoQ: 6 mg/dL
Hook Effect	Not tested	No hook effect up to 190 mg/dL
Expected Values	cutoff point: 30 mg/dL Reference ranges have not been established for this assay for different ethnic populations or disease states. Since Lp(a) levels are largely influenced by hereditary factors and vary with ethnic populations, it is recommended that each laboratory establish its own expected values.	same

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Comparison of assays – similarities and differences

(continued)

Assay Comparison

Feature	Lp(a)-Latex Seiken assay (predicate device: k013359)	TQ Lp(a) Gen.2 assay (candidate device)
Precision	Within-run precision:	Repeatability = Within-run precision:

	Mean	SD	CV
Control I	21.9 mg/dL	0.438	2.00%
Control II	54.7 mg/dL	0.686	1.26%

	Mean	SD	CV
Control L	20.3 mg/dL	0.3	1.4%
Control H	61.5 mg/dL	0.6	1.0%
Pool 1	7.0 mg/dL	0.4	5.4%
Pool 2	16.1 mg/dL	1.0	6.2%
Pool 3	30.9 mg/dL	0.7	2.4%
Pool 4	79.4 mg/dL	0.7	0.9%

Between-run precision:

	Mean	SD	CV
Control I	18.7 mg/dL	0.40	2.12%
Control II	41.5 mg/dL	0.44	1.06%
Pool 1	8.4 mg/dL	0.19	2.22%
Pool 2	26.5 mg/dL	0.29	1.11%
Pool 3	66.3 mg/dL	0.66	0.99%

Intermediate Precision = Total precision/Between-run precision

	Mean	SD	CV
Control L	20.3 mg/dL	0.3	1.6%
Control H	61.5 mg/dL	0.7	1.1%
Pool 1	7.0 mg/dL	0.5	7.6%
Pool 2	16.1 mg/dL	1.0	6.4%
Pool 3	30.9 mg/dL	0.9	2.9%
Pool 4	79.4 mg/dL	0.9	1.1%

Continued on next page

Comparison of assays – similarities and differences

(continued)

Assay Comparison		
Feature	**Lp(a)-Latex Seiken assay (predicate device: k013359)**	**TQ Lp(a) Gen.2 assay (candidate device)**
Interferences and cross reactivity	Icterus (conjugated and unconjugated bilirubin): no significant interference up to 30 mg/dL Hemolysis: no significant interference up to 500 mg/dL Triglycerides: no significant interference up to 1500 mg/dL Plasminogen: no significant interference up to 200 mg/dL Apolipoprotein B: no significant interference up to 200 mg/dL	Icterus (conjugated and unconjugated bilirubin): no significant interference up to an I index of 60 (approximately 60 mg/dL) Hemolysis: no significant interference up to an H index of 1000 (approximately 1000 mg/dL) Lipemia: no significant interference up to an L index of 2000 Plasminogen: no significant cross reactivity up to 150 mg/dL Apolipoprotein B: no significant cross reactivity up to 200 mg/dL Rheumatoid Factor: no significant interference up to 1200 IU/mL Drugs: No interference was found at therapeutic concentrations using common drug panels

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Comparison of calibrators – similarities and differences

Calibrator Comparison		
Feature	**Diazyme Lp(a) calibrator (predicate device: k082488)**	**Preciset Lp(a) Gen.2 calibrator set (candidate device)**
Intended use	The Diazyme Lp(a) calibrator set is intended for use in establishing the calibration curve for the Diazyme Lp(a) reagents by turbidimetry.	The Preciset Lp(a) Gen.2 calibrator set is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.
Analyte	Lipoprotein (a)	same
Format & matrix	Consists of 5 lyophilized human serum calibrators	Consists of 5 lyophilized human plasma calibrators
Storage	2-8°C	same

Comparison of controls – similarities and differences

Control Comparison		
Feature	**Diazyme Lp(a) control set (predicate device: k082488)**	**PreciControl Lp(a) Gen.2 control set (candidate device)**
Intended use	The Diazyme control set is intended for use in monitoring the quality control of results obtained with the Diazyme Lp(a) reagents by turbidimetry.	The PreciControl Lp(a) Gen.2 control set is intended for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Analyte	Lipoprotein (a)	same
Format & matrix	Consists of 2 lyophilized human serum controls	Consists of 2 lyophilized human plasma controls
Storage	2-8°C	same

Continued on next page

Section 4 - 510(k) Summary: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System, Continued

Evaluations summary

(1) The **cobas c** Tina-quant Lipoprotein (a) Gen.2 assay was evaluated for several performance characteristics, including precision, LoB, LoD, LoQ, high dose hook effect, cross reactivity, method comparison, interfering substances, anticoagulants, linearity, reagent on-board stability, and reagent shelf life stability.

(2) The Preciset Lp(a) calibrator set was evaluated for value assignment and stability.

(3) The PreciControl Lp(a) control set was evaluated for value assignment and stability.

A summary of the evaluation studies is provided in Section 5-Analytical Performance Characteristics.

Confidentiality

Roche Diagnostics requests that the FDA not disclose the nature or existence of the premarket notification until the substantial equivalence decision has been reached.

Closing

We trust that the information provided in this Premarket Notification [510(k)] will support a determination of substantial equivalence for the **cobas c** Tina-quant Lipoprotein (a) Gen.2 test system.

If you should have questions or required further information, please do not hesitate to contact this office.

Lisa K. Klinedinst
Roche Diagnostics
Regulatory Affairs Consultant
Phone: 317-521-1942
Fax: 317-521-2324

Date prepared: November 28, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 29, 2012

Roche Diagnostics
c/o Lisa K. Klinedinst
9115 Hague Road, Building A
Indianapolis, IN 46250-0416

Re: k122722
Trade/Device Name: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System
Preciset Lp(a) Gen.2 calibrator set
PreciControl Lp(a) Gen.2 control set
Regulation Number: 21 CFR 866.5600
Regulation Name: Low Density Lipoprotein Immunological Test System
Regulatory Class: Class II
Product Code: DFC, JIT, JJX
Dated: August 31, 2012
Received: September 5, 2012

Dear Ms. Klinedinst:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122722

Device Name: cobas c Tina-quant Lipoprotein (a) Gen.2 Test System
Preciset Lp(a) Gen.2 calibrator set
PreciControl Lp(a) Gen.2 control set

Indications for Use:

The cobas c Tina-quant Lipoprotein (a) Gen.2 assay is an in vitro test intended for the quantitative determination of lipoprotein(a) [Lp(a)] in human serum and plasma on the Roche/Hitachi cobas c systems. The measurement of Lp(a) is useful in evaluation of lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation and other lipoprotein tests.

The Preciset Lp(a) calibrator set is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

The PreciControl Lp(a) Gen.2 control set is intended for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Prescription Use __X____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k122722