510(k) Summary

Date of summary: December 6, 2007

APR 14 2008

Product Name: HDL Cholesterol Reagent

Manufacturer: Medica Corporation
5 Oak Park Drive
Bedford, MA 01730

Correspondent: Photios Makris
Director QA/RA
Medica Corporation
5 Oak Park Drive
Bedford, MA 01730

Substantial Equivalent Device:

Manufacturer: Genzyme Corporation
Product: Cobas Ready HDL Cholesterol Reagent

Product Attribute	Medica HDL Cholesterol Reagent	Genzyme HDL Cholesterol Reagent for Cobas-Mira	Substantial Equivalent
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of High Density Lipoprotein (HDL) in human serum using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of High Density Lipoprotein (HDL) in human serum using the Roche Cobas-Mira chemistry analyzer.	√
Sample	Serum	Serum	√
Test Methodology	EasyRA ready-to-use enzymatic assay reagent	Cobas-Mira ready-to-use enzymatic assay reagent	√

Intended Use: The EasyRA HDL cholesterol reagent is intended for the quantitative determination of High Density Lipoprotein Cholesterol in human serum, using the Medica "EasyRA Chemistry analyzer" in clinical laboratories to screen for low HDL levels as a risk factor in coronary artery disease.

For *in-vitro* diagnostic use only. For professional use only

Methodology: Medica's HDL cholesterol reagent consists of two parts R1 and R2. The first step involves the removal of other non-HDL lipoproteins via selective reaction with reagent R1. In the second step, the selective detergent in R2 solubilizes the HDL cholesterol specifically, which then reacts with a chromagen to develop a color that can be read optically at 600nm. The intensity of the color is proportional to the concentration of HDL cholesterol in the sample.

Performance Data:

Linearity:

Linearity studies, based on CLSI EP-6A, were performed using NIST-traceable commercial linearity standards on the EasyRA Chemistry analyzers. The HDL cholesterol reagent is linear from 2 to 150mg/dL.

Within-Run Precision:

Within-run precision was determined following CLSI EPA-A2. Five replicates of two levels of a commercial serum-based Quality control material were tested each day for five days on three analyzers.

EasyRA HDL cholesterol reagent Within-run precision

	Bio-Rad L1		Randox L2	
	EasyRA #2	EasyRA #3	EasyRA #2	EasyRA #3
Grand Mean	32.5	32.1	64.3	62.8
Std. Dev.	0.63	0.69	0.94	0.62
CV%	1.9%	2.2%	1.5%	1.0%

Total Precision:

Total precision was determined following CLSI EPA-A2. Two levels of a commercial serum-based Quality control material were tested in duplicate twice daily for 20 days on three EasyRA nalyzers.

	Bio-Rad L1		Randox L2	
	EasyRA #2	EasyRA #3	EasyRA #2	EasyRA #3
Grand Mean	33.1	33.2	64.6	64.2
Std. Dev.	0.82	0.84	1.37	
CV%	2.47%	2.51%	2.12%	1.91%

Method Comparison:

Method comparison was based on EP7-A. At least 40 samples were tested in two EasyRA analyzers using Medica's reagent and in duplicate on a Cobas Mira analyzer using the Genzyme reagent. Medica's HDL cholesterol reagent correlated excellently with the predicate device.

Sample carryover:

Sample carryover, within run drift, was tested based on CLSI EP10-A2. Eleven samples were analyzed that are L (low), M (mid-range) and H (high) range in a predefined sequence twice in a single day. There was no evidence of sample carryover.

Sensitivity:

The limit of detection, or analytical sensitivity, was determined by testing 20 replicates of reagent grade water, then calculating the mean plus two standard deviation units (mean + 2SD). The functional sensitivity was determined as the reagent grade water mean, as determined above, plus seven standard deviation units (mean + 7SD).

The analytical sensitivity of the EasyRA HDL cholesterol reagent is 0.86 mg/dl and the lower limit of detection is 1.3 mg/dl.

Interference testing:

Testing for interference substances was based on CLSI EP-7A. The following substances were tested: Hemoglobin to 500 mg/dl; Billirubin to 20 mg/dl; and Lipemia (using intralipid).

Hemoglobin	No interferences up to 500mg/dl
Billirubin	No interferences up to 32.5mg/dl
Lipemia	No interferences up to 1000mg/dl

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Medica Corp.
c/o Photios Makris
5 Oak Park Drive
Bedford, MA 01730

APR 14 2008

Re: k073497
Trade/Device Name: Hdl Cholesterol Reagent, Model 10211
Regulation Number: 21 CFR §862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, meets the limitations to exemption in 21 CFR 862.9(c)(4)
Product Code: LBS, JIT
Dated: February 28, 2008
Received: March 03, 2008

Dear Mr. Makris:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: k073497

Device Name: EasyRA HDL Cholesterol Reagent

Indications for Use:

The EasyRA HDL Cholesterol reagent is intended for the quantitative determination of High Density Lipoprotein Cholesterol in human serum on the Medica EasyRA Chemistry Analyzer. The Medica EasyRA HDL-Cholesterol reagent can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease.

Device Name: EasyRA HDL Cholesterol Calibrator

Indications for Use:

The EasyRA HDL Cholesterol calibrator is intended for the one point calibration of the HDL reagent prior to patient serum sample analysis on the EasyRA clinical chemistry analyzer.

For *in-vitro* diagnostic use only. For Professional use only.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K073497