510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k073497

B. Purpose for Submission:

Notification of intent to manufacture and market new devices for the determination of High Density Lipoprotein Cholesterol in Serum.

C. Measurand:

High Density Lipoprotein Cholesterol (HDL)

D. Type of Test:

Colorimetric Trinder reaction

E. Applicant:

Medica Corporation

F. Proprietary and Established Names:

Proprietary Name – Medica Corporation EasyRA HDL-Cholesterol Reagent
Established Name – HDL Cholesterol

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1475: Lipoprotein Test System
   21 CFR 862.1150: Calibrator

2. Classification:

   Class II – Medica Corporation HDL Calibrator
   Class I (meets the exemptions 21 CFR 862.9(c)(4)) – Medica Corporation EasyRA HDL-Cholesterol Reagent

3. Product code:

   Medica Corporation EasyRA HDL-Cholesterol – LBS
   Medica Corporation EasyRA HDL- Cholesterol Calibrator – JIT

4. Panel:

   75 - Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use

2. Indication(s) 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.

   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.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   For use on the EasyRA Chemistry Analyzer.

I. Device Description:

The Medica EasyRA HDL cholesterol reagent consists of two reagents, R1 and R2..
The direct assay method involves the removal of non-HDL lipoproteins via R1. The
second step of the assay involves R2 which contains a detergent which selectively
solubilizes HDL. HDL then reacts with a chromagen to develop a color at 600nm.

This device has been certified by the Cholesterol Reference Method Laboratory
Network.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Ultra N-Geneous HDL Cholesterol Reagent and calibrator.

2. Predicate K number(s):

   k021316

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indication 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.	For the quantitative determination of high density lipoprotein cholesterol (HDL-C) in human serum or plasma
Type of Test	Quantitative	Quantitative
Specimen Type	Serum	Serum or Plasma
Calibrator	Lyophilized	Lyophilized

K. Standard/Guidance Document Referenced (if applicable):

The following standards have been used to support this submission:

CLSI:

EP05-A2 – Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

EP06-A - Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

EP7-P Interference Testing in Clinical Chemistry Approved Guideline – Second Edition

EP09-A2 – Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline -Second Edition

EP10-A3 - Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures

EP17-A - Protocols for Determination of Limits of Detection

EP21-A - Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline

L. Test Principle:

Colorimetric Trinder reaction (Cholesterol Oxidase and Cholesterol Esterase)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

Total and within run precision were determined based upon CLSI EP5-A2. Three levels of commercial serum based quality control material were tested on multiple EasyRA analyzers (Level 1 and 2 on EasyRA #2, Easy RA #3 and Level 3 on EasyRA #2, Easy RA #3, and analyzer 08011000).

Within Run Precision

	Level 1		Level 2		Level 3		
	EasyRA #2	EasyRA #3	EasyRA #2	EasyRA #3	PP03	PP11	08011000
N	80	80	80	80	80	80	80
Mean	64.6	64.2	33.1	33.2	38.7	38.8	39.6
SD	0.96	0.83	0.46	0.65	0.62	0.43	0.79
CV%	1.49	1.29	1.39	1.96	1.61	1.12	2.00

Total Precision

	Level 1		Level 2		Level 3		
	EasyRA #2	EasyRA #3	EasyRA #2	EasyRA #3	PP03	PP11	08011000
N	80	80	80	80	80	80	80
Mean	64.6	33.1	64.2	33.2	38.7	38.8	39.6
SD	1.37	0.82	1.22	0.83	0.89	0.72	1.21
CV%	2.12	2.47	1.91	2.51	2.27	1.86	3.05

b. *Linearity/assay reportable range:*

Linearity determination was based upon CLSI EP6-A and was performed separately on two Medica EasyRA analyzers. Each level was measured in duplicate. Nine samples were serially diluted from a level of 150 to 2 mg/dL. The linerar regression results for analyzer 1 were y=1.0289x-1.1945, r^2=0.9999, and for analyzer 2 were y=1.0066x-0.8358, r^2=0.9994.

The claimed reportable range of the assay is 2 – 150 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Accelerated stability studies were performed using acceptable protocols for on-board and shelf life stability. Real-time studies are on-going.
The stored stability (shelf-life) is 24 months and the on-board stability is 24 days when stored at 2 – 8°C.

The EasyRA HDL-Cholesterol calibrator was previously cleared under k021316.

d. *Detection limit:*

Twenty replicates of water were analyzed on three EasyRA analyzers to determine the Limit of Blank. A serum sample was prepared with a value close to the lower measuring range of the assay. The sample was analyzed twenty times on three EasyRA analyzers to determine performance with a low concentration sample. The limit of a blank sample is 1.3 mg/dL. The low end of the claimed measuring range is 2 mg/dL.

e. *Analytical specificity:*

To determine the level of interference from substances normally present in human serum, the Medica EasyRA HDL-Cholesterol Assay was tested with normal serum samples containing about 39 mg/dL HDL-C spiked with various concentrations of potentially interfering substances following CLSI guideline EP7-A on the Medica EasyRA Chemistry Analyzer. The following substances normally present in serum produced less than 10% deviation when tested at levels equal to the following concentrations:

Interference Substance	Concentration
Bilirubin	32.50 mg/dL
Hemoglobin	500 mg/dL
Lipemia using Intralipid	1000 mg/dL

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A total of 61 samples were tested on the device and compared with results on the same samples tested using a predicate assay on the Cobas Mira. Samples ranged from 2 to 148 mg/dL. The resulting regression statistics are as follows: $y = 0.93x + 1.8$, $r^2 = 0.9976$. Samples within the clinically relevant range between 2 and 80 mg/dL demonstrated linear regression results of $y = 0.965x + 0.37$, $r^2 = 0.9965$.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Less than 40 mg/dL – A risk factor for heart disease

60 mg/dL and above – Considered protective against heart disease

* Third report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and treatment of High Blood Cholesterol in Adults (NCEP ATPIII)

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.