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

A. 510(k) Number:
k051121

B. Purpose for Submission:
New submission

C. Measurand:
LDL Cholesterol

D. Type of Test:
Photometric, Quantitative

E. Applicant:
TECO DIAGNOSTICS

F. Proprietary and Established Names:
Direct LDL Cholesterol, Model L530-60H

G. Regulatory Information:
1. Regulation section:
   21CFR Sec.- 862.1475-Lipoprotein test system
   21CFR 862.9(c)(4)
2. Classification:
   Class 1 (meets limitations of exemptions)
3. Product code:
   MRR - System, Test, Low Density, Lipoprotein
4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See Indications for use below
2. Indication(s) for use:
   For the quantitative determination of Low-density lipoprotein cholesterol (LD-C) in human serum or plasma. LDL Cholesterol is recognized as a useful tool in identifying patients who are at a higher risk for coronary heart disease. High LDL cholesterol levels are associated with an increased risk. This reagent set is intended for *in vitro* diagnostic use only.
3. Special conditions for use statement(s):
   Prescription use
4. Special instrument requirements:
   Manual or automated analyzer

I. Device Description:

The Direct LDL Cholesterol assay is a homogeneous method for directly measuring serum LDL-C levels without the need for any off-line pretreatment or centrifugation steps. The method is in a two-reagent format. The first reagent contains α-cyclodextrin and dextran sulfate to stabilize LDL, VLDL, and chylomicrons. The second reagent contains PEG modified enzymes that selectively react with the cholesterol present in the LDL particles. Consequently, only the LDL cholesterol is subject to cholesterol measurement.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Pointe Scientific, Inc., AutoLDL Cholesterol Reagent Set
2. Predicate 510(k) number(s):
   k981978
3. Comparison with predicate:

   The Direct LDL Cholesterol Reagents are substantially equivalent to other devices legally marketed in the United States. The applicant compared TECO Diagnostics Direct LDL Cholesterol reagents to Pointe Scientific AutoLDL Cholesterol Reagent Set (k981978). Both devices are for the quantitative determination of the same analyte in the same matrixes. Both devices are based on enzymatic colorimetric reaction using two-reagent reaction sequence.

Feature	Candidate Device		Predicate Device		
Precision Within-Day	Sample 1 N=25 Mean=178 SD=3.12 CV%=1.7	Sample 2 N=25 Mean=33 SD=0.6 CV%=1.8	Sample 1 N=20 Mean=37 SD=1.5 CV%=4.1	Sample 2 N=20 Mean=122 SD=4.2 CV%=3.4	Sample N=20 Mean=187 SD=6.3 CV%=3.4
Day to Day	Sample 1 N=25 Mean=174.2 SD=5.04 CV%=2.8	Sample 2 N=25 Mean=32.7 SD=0.9 CV%=2.7	Sample 1 N=20 Mean=38 SD=2.1 CV%=5.4	Sample 2 N=20 Mean=135 SD=7.9 CV%=5.9	Sample N=20 Mean=222 SD=7.5 CV%=3.4

Feature	Candidate Device	Predicate Device
Linearity	5-500 mg/dL	0-700 mg/dL
Sensitivity	1 mg/ dL	1 mg/dL

Accuracy	R=0.987 Y=0.94X +3.39	R=0.962 Y=0.92 X+5.22
Expect values/ Reference range	<130 mg/dL	<130 mg/dL
Calibrator	The value of this calibrator was assigned by procedures traceable to the NRS/CHOL	Auto HDL/LDL Calibrator (k981978)

K. Standard/Guidance Document Referenced (if applicable):
NCCLS EP5-A – Evaluation of Precision Performance of Clinical Chemistry Devices
NCCLS EP6-P – Evaluation of Linearity of Quantitative Analytical Methods
NCCLS EP9-A – Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:
The Direct LDL Cholesterol assay is a homogeneous method for directly measuring serum LDL-C levels without the need for any off-line pretreatment or centrifugation steps. The method is in a two-reagent format. The first reagent contains α-cyclodextrin and dextran sulfate to stabilize LDL, VLDL, and chylomicrons. The second reagent contains PEG modified enzymes that selectively react with the cholesterol present in the LDL particles. Consequently, only the LDL cholesterol is subject to cholesterol measurement.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
    a. *Precision/Reproducibility:*
    Within-day precision was determined by following a modification of NCCLS EP5A. Two commercially available (human) control materials were assayed 25 times on the Hitachi 717. The run to run precision was determined by following a modification of NCCLS EP5A. Two commercially available (human) serum control materials were assayed on the Hitachi 717 five times per day for five days for a total of 25 values. The results are presented in the table below:

Precision Within-Day	Sample 1 N=25 Mean=178 SD=3.12 CV%=1.7	Sample 2 N=25 Mean=33 SD=0.6 CV%=1.8
Day to Day	Sample 1 N=25 Mean=174.2 SD=5.04 CV%=2.8	Sample 2 N=25 Mean=32.7 SD=0.9 CV%=2.7

    b. *Linearity/assay reportable range:*
    Linearity studies were designed using NCCLS EP6-P. Serial dilutions of high serum samples were used. The following results were obtained from the Linearity test of Direct LDL Cholesterol Reagent Set. The test was performed using the Hitachi 717 Chemistry Autoanalyzer. Values were

plotted versus the samples dilution and an appropriate line fitted by standard linear regression. Y=0.96X-7.26, r = 0.999, demonstrating the linearity of this test is up to 500 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Subject of k050823 Teco, Direct HDL cholesterol and direct HDL/LDL calibrator

d. *Detection limit:*
Two samples, a zero and a 1 mg/ dL were assayed six times. The samples were detected with 95% confidence as 0 to 0.2 mg/dL for the zero sample and 0.4 to 1.6 mg/dL for the 1 mg/dL sample. The claimed assay range is 5 to 500 mg/dL.

e. *Analytical specificity:*

Substance	Maximum Level	Observed Effect on Analyte
Hemoglobin	400 mg/dL	No Significant interference (within 5mg/dL or <5%)
Bilirubin	20 mg/dL	No Significant interference (within 5mg/dL or <5%)
Triglyceride	1500 mg/dL	No Significant interference (within 5mg/dL or <5%)

f. *Assay cut-off:*
Not Applicable

2. <u>Comparison studies:</u>
a. *Method comparison with predicate device:*
Method comparison experiments were designed using NCCLS EP9-A and employed Excel regression to assess the data. Comparison study was performed on the Hitachi 717 Chemistry Analyzer following instructions for automatic procedure. The predicate Pointe Scientific AutoLDL Cholesterol Reagent Set (k981978) was used to compare with Teco Direct LDL Cholesterol Reagent Set. There were 52 serum samples with LDL cholesterol values ranging from 34.5 to 270.3 mg/dL in the study.

R=0.987
Y=0.94X +3.39

b. *Matrix comparison:*
Matrix comparison study in which one sample was split as follows:
(Total test 6 samples)

	Serum mg/dL	Plasma mg/dL		
		Sodium Heparin	Lithium Heparin	EDTA
1	164	171	173	173
2	142	144	141	143

3	112	114	111	113
4	33	33	32	33
5	74	74	73	74
6	54	54	55	54
		R=0.999	R=0.998	R=0.999

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:
   NCEP recommendations

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.