

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

A. 510(k) Number:

k051619

B. Purpose for Submission:

Clearance of new calibrator for a device

C. Measurand:

Calibrators for Apolipoprotein A1 (apoA1), Apolipoprotein B (apoB), and HDL Cholesterol

D. Type of Test:

Calibrator

E. Applicant:

Bayer HealthCare LLC

F. Proprietary and Established Names:

Lipoprotein Calibrator

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1150, Calibrator
2. Classification:
Class II
3. Product code:
JIX, Calibrator, multi-analyte mixture
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

The Bayer Lipoprotein Calibrator is intended for *in vitro* diagnostic use to calibrate Apolipoprotein A1, Apolipoprotein B, and the Direct HDL assays on the ADVIA IMS Chemistry systems.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use on the ADVIA IMS Chemistry systems

I. Device Description:

Lipoprotein Calibrator is a human serum based solution containing various non human and human constituents.

All human source materials were tested by FDA-approved methods and found to be nonreactive for HBsAg, HCV, and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Lipoprotein Calibrator

2. Predicate 510(k) number(s):

k031682

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Calibration of assays	Same
Format	A lyophilized mixture of human and bovine serum and bovine constituents has been added to achieve specific concentrations.	Same
Analytes Measured	Apolipoprotein A1 Apolipoprotein B HDL Cholesterol	Apolipoprotein A1 Apolipoprotein B

Similarities		
Item	Device	Predicate
Stability	<u>Unopened:</u> Stable at 2-8°C until the expiration date printed on the label	Same
Stability	<u>Reconstituted:</u> 3 days at 2-8°C	Same
Levels	Six levels for apoA1 and apoB, and a single level for Direct HDL Chol	Six levels for apoA1 and apoB

Differences		
Item	Device	Predicate
Direct HDL Cholesterol	Addition of assigned value	Analyte present in the calibrator but no value was assigned

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

FDA Guidance “Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators”, February 22, 1999

L. Test Principle:

Not applicable. This submission is for clearance of a calibrator.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

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

The apoA1/apoB values of the calibrator are traceable to the WHO-IFCC international reference materials (SP1-01/SP3-07).

The values for the Direct HDL Cholesterol were derived from human serum correlation studies versus the Designated Comparison Method of the National Cholesterol Education Program.

Stability testing protocols and acceptance criteria were reviewed and found acceptable. Stability is performed on 3 lots of material. After real time stability studies, the product was assigned 24 months stability. After reconstitution, the calibrator is stable for 3 days at 2 – 8°C.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

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:

Not applicable

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.