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510(k) Summary

K963813

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

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2) Device name

Proprietary name: Boehringer Mannheim Direct HDL-Cholesterol

Common name: HDL test

Classification name: LDL and VLDL precipitation, cholesterol via esterase-oxidase, HDL

3) Predicate device

We claim substantial equivalence to the Boehringer Mannheim HDL Cholesterol

4) Device Description

The Direct HDL test principle use PEG-modified enzymes and sulfated cyclodextrin. When cholesterol esterase and cholesterol oxidase enzymes are modified by PEG, they show selective catalytic activities toward lipoprotein fractions, with the rectivity increasing in the order LDL < VLDL ≈ chylomicrons < HDL.

5) Intended use

Boehringer Mannheim Direct HDL is intended for the quantitative determination of high-density lipoprotein Cholesterol (HDL-C) in serum and plasma.

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6) Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Direct HDL	HDL Cholesterol
Lower Detection Limit	3 mg/dl	3 mg/dl
Linearity	0 - 185 mg/dl	3 - 150 mg/dl
Method Comparison	vs. HDL Cholesterol liquid (Passing-Bablock) n = 110 slope = 1.02 intercept = 0.55 Sy.x = 3.009 r = 0.95 range = 4.8 - 74.4	vs. HDL Cholesterol powder (Passing-Bablock) n = 75 slope = 1.008 intercept = 0.392 Sy.x = 0.597 r = 0.999 range = 6.6 - 125.6
Interfering substances	hemoglobin > 1000 mg/dl bilirubin > 65 mg/dl lipemia > 600 mg/dl	hemoglobin > 79 mg/dl bilirubin > 4 mg/dl lipemia - not tested