

**SPECIAL 510(k): Device Modification**  
**OIR Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE

**RE:** DOCUMENT NUMBER k130295

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: **LipidPro® Lipid Profile and Glucose Measuring System (k090405)**.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for:

- Name change from LipidPro® Lipid Profile and Glucose Measuring System to LipidPro® Lipid Profile and Glucose Measuring System (for single patient use only) and LipidPro® Professional Lipid Profile and Glucose Measuring System (for multiple patients use), in order to distinguish the two separate systems.
  - adding strip error message for all different lipid test strips
  - adding a check strip for use with the LipidPro® Lipid Profile tests
  - changing the button utilized to enter memory mode
  - modifying the design of the strip cover (for all five test strips) and the capillary rod for use with the Lipid Profile tests only
  - changing the raw material of all control solution bottles, including: total cholesterol (TC); high-density lipoprotein cholesterol (HDL-C), triglyceride (TG) and glucose control solution
  - renaming all control solutions (Total Cholesterol Control Solution, HDL Cholesterol Control Solution, Triglyceride Control Solution, and Glucose Control Solution) from low, medium, and high to Level 1, 2, and 3
  - The volume of the control solutions has changed from 1 mL per bottle to 3 mL per bottle
  - adding foil pouch package in addition to vial package for all the test strips
  - adding a print option and printing/ data transfer to PC error message
  - adding an option to select temperature unit (Fahrenheit v.s. Celsius).
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics.
  5. A **Design Control Activities Summary** which includes:
    - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
    - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
    - c) A declaration of conformity with design controls. The declaration of conformity should include:

- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
- ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

**6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

These devices are intended for either single-patient use only (LipidPro System) or for multiple-patient use (LipidPro Professional System). Disinfection efficacy studies were performed in k103021 on materials comprising the meter and lancing device by an outside commercial testing laboratory demonstrating complete inactivation of live hepatitis B virus with CaviWipes Disinfecting Towelettes (EPA Reg. No. 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for each of the meters after 10,950 cleaning and disinfection cycles and after 1,098 cleaning and disinfection cycles for the lancing device (for use only with the single-patient use system) designed to simulate 3 years of use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.