5. 510(k) Summary

DEC 2 1 2010

510(k) number: K102702

Date Prepared: 17 September 2010

Submitter:	Alere San Diego, Inc.	**Contact:**	Edward Brehm
Address:	9975 Summers Ridge Road		Regulatory Affairs Manager
	San Diego, CA 92121	**Telephone:**	858 805 3071
Telephone:	858 805 3071	**Fax:**	858 695 7100
Fax:	858 695 7100	**Email:**	ed.brehm@alere.com

Trade name:	**Common Name (Device Type):**
Alere Cholestech LDX® Lipid Controls Alere Cholestech LDX® Multianalyte Controls Alere Cholestech LDX® Calibration Verification	Assayed Quality Control materials

Class:	1
Regulation number:	21 CFR 862.1660
Product Code:	JJY
Panel:	Clinical Chemistry

Predicate devices:
K913687 CHEM-CHEX (Streck Laboratories, Inc.)

5.1. Intended Use / Indications for Use:

Lipid Controls:

Intended Use: Assayed quality control materials for use with the Alere Cholestech LDX® system.

Indications for Use: Alere Cholestech LDX® Level 1 and Level 2 Controls are designed to be used only for monitoring the performance of test procedures on the Alere Cholestech LDX® System.

Multianalyte Control:

Intended Use: Assayed quality control materials for use with the Alere Cholestech LDX® system.

Indications for Use: Alere Cholestech LDX® Level 1 and Level 2 Controls are designed to be used only for monitoring the performance of test procedures on the Alere Cholestech LDX® System.

Calibration Verification:

Intended Use: Assayed calibration verification material is designed to be used for verifying the reportable range of tests on the Alere Cholestech LDX® System.

Indications for Use: This material is designed for use with any Alere Cholestech LDX® cassette type that includes total cholesterol, HDL cholesterol, triglycerides and glucose.

5.2. Summary of Changes from Predicate Device:

The predicate devices are the Lipid Controls, Multianalyte Controls and Calibration Verification Materials manufactured by Streck for Alere. Streck will no longer be the OEM manufacturer for Alere San Diego. Streck has transferred the responsibility for manufacturing the controls from the Streck manufacturing site (Omaha, Nebraska) to the Alere manufacturing site (San Diego, California). All raw materials, vendors, raw material specifications, generic manufacturing processes, in-process test methods, final release test methods, release specifications and methods of value assignment are unchanged.

5.3. Substantial Equivalence to Predicate Device:

The predicate devices are the Lipid Controls, Multianalyte Controls and Calibration Verification Materials manufactured by Streck. The Lipid Controls, Multianalyte Controls and Calibration Verification Materials manufactured by Alere San Diego are substantially equivalent to the Multianalyte Controls manufactured by Streck in intended use, technology and performance. Bench performance testing was performed comparing the new device and the predicate device, and was found to be substantially equivalent.

5.4. List of Similarities:
Intended use is unchanged
Indications for use is unchanged
The operating principle is unchanged
The technology is unchanged
The analytical performance is unchanged or improved
The manufacturing process is unchanged
The formulation is unchanged

5.5. List of Differences:
None

5.6. Conclusion:
Performance testing demonstrates that the Lipid Controls, Multianalyte Controls and Calibration Verification Materials manufactured by Alere San Diego are as safe, as effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Alere San Diego Inc.
c/o Mr. Edward C. Brehm
Regulatory Affairs Specialist
9975 Summers Ridge Road
San Diego, CA 92121

DEC 2 1 2010

Re: k102700
Trade Name: The Alere Cholestech LDX Lipid Controls, The Alere Cholestech LDX Multianalyte Controls, The Alere Cholestech LDX Calibration Verification
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: November 18, 2010
Received: November 19, 2010

Dear Mr. Brehm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

DEC 2 1 2010

510(k) Number (if known): K102700
Device Name: Alere Cholestech LDX® Lipid Controls, Alere Cholestech LDX® Multianalyte Controls, and Alere Cholestech LDX® Calibration Verification

Indications for Use:

Lipid Controls: Alere Cholestech LDX® Lipid Controls, Level 1 and Level 2, are designed to be used only for monitoring the performance of test procedures on the Alere Cholestech LDX® System.

Multianalyte Controls: Alere Cholestech LDX® Multianalyte Controls, Level 1 and Level 2, are designed to be used only for monitoring the performance of test procedures on the Alere Cholestech LDX® System.

Calibration Verification Materials: Alere Cholestech LDX® Calibration Verification, Levels 1 – 4, are designed to be used for verifying the reportable range of tests on the Alere Cholestech LDX® System. This material is intended for use with any Alere Cholestech LDX® cassette type that includes total cholesterol, HDL cholesterol, triglycerides and glucose.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use n/a (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K102700