SECTION V

JUL 2 4 2012

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K121759

Submitter:
Cone Bioproducts
1012 N. Austin Street
Seguin, TX 78155

Telephone: (830)379-0197
Facsimile: (830)379-0471

Contact Person:

William K. Cone
President
Telephone: (830)379-0197 ext. 203
Facsimile: (839)379-0471

Preparation Date:

June 1, 2012

Device Information:

Proprietary Name:	CONE-TROL Liquid Chemistry Control
Regulation Section:	21 CFR 862.1660 Control
Product Code:	JJY – Multi-analyte Control
Classification:	Class I, Reserved
Panel:	Clinical Chemistry (75)

Device to Which Substantial Equivalence is Claimed:

Liquid Assayed Multiqual Control Levels 1, 2, and 3
Bio-Rad Laboratories
Irvine, California
510(k) Number: k011867

Device Description:

CONE-TROL Liquid Chemistry Control is prepared from human serum to which purified biochemical material (human and animal origin), chemicals, drugs, preservatives, and stabilizers have been added. The control is provided in liquid form for user convenience.

Intended Use:

CONE-TROL Liquid Chemistry Control is a human liquid control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

Comparison to Predicate Device(s):

The CONE-TROL Liquid Chemistry Control is substantially equivalent to Liquid Assayed Multiqual Control (k011867) for its stated intended use.

Table V-1: Device Comparison Table

Device Characteristics	Subject Device	Predicate Device(s) k011867
Intended Use	CONE-TROL Liquid Chemistry Control is a human liquid control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Liquid Assayed Multiqual Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Analyte(s)	Albumin, Alkaline Phosphatase, Alanine Aminotransferase, Amylase, Apolipoprotein A-1, Apolipoprotein B, Aspartate Aminotransferase, Bicarbonate, Bilirubin-Direct, Bilirubin-Total, Blood Urea Nitrogen, Complement 3, Complement 4, C-Reactive Protein, Calcium, Cholesterol, HDL Cholesterol, LDL Cholesterol, Cholinesterase, Creatinine Kinase, Chloride, Creatinine, Gamma Glutamyltransferase, Glucose, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Lactate, Lactate Dehyrdogenase, Haptoglobin, Iron, Unsaturated Iron Binding Capacity, Magnesium, Phosphorous, Potassium, Prealbumin, Sodium, Total Protein, Transferrin, Triglycerides, Uric Acid	All analytes in subject device plus the analytes listed below : Acetaminophen, Acid Phosphatase, α-1-Antitrypsin, αHBDH, Amikacin, Carbamazepine, Ceruloplasmin, CK-MB, Copper, Cortisol, Digoxin, Ethanol, Gentamicin, Globulin, Iron Binding Capacity-Total, LAP Arylamidase, Lipase, Lithium, Osmolality, Phenobarbital, Phenytoin, Phospholipids, Prostatic Acid Phosphatase, Protein Electrophoresis, Salicylate, T3-Total, T3-Free, T4-Total, T4- Free, T-Uptake, Theophylline, Thyroid Stimulating Hormone, Tobramycin, Urea, Valproic Acid, Vitamin B12, Zinc
Matrix	Human Serum	Human Serum
Control Form	Liquid	Liquid
Levels	2	3
Storage (Unopened Frozen)	-20°C or colder Until expiration date	-20°C or colder Until expiration date

Storage (Unopened Thawed)	2-8°C 30 days	2-8°C (current Package Insert) 30 days with the following exceptions: Direct Bilirubin - 11 days, Triglycerides, HDL, Cholinesterase, and Phosphorous - 7 days. Total and Direct Bilirubin values may decrease, Alkaline phosphatase activity may rise. The control must be stored frozen when using AST methods without pyridoxal-5-phosphate.
Storage (Open, Thawed)	2-8°C for 14 days.	2-8°C (current Package Insert) 14 days with the following exceptions: Direct Bilirubin, Triglycerides, HDL, Cholinesterase, and Phosphorous will be stable for 7 days and LAP Arylamidase will be stable for 3 days.

Value Assignment

CONE-TROL Liquid Chemistry Control is value assigned on the Abaxis Piccolo Express Analyzer using Piccolo Xpress panels. Each panel is a self-contained plastic disc with reagents. Intelligent Quality Control and bar coded calibration are built in to each reagent disc. The panels used to value assign CONE-TROL Liquid Chemistry Control include but are not limited to: Lipid Panel Plus, Cat. No. 400-0030; Hepatic Panel, Cat. No. 400-0026; General Chemistry 13, Cat. No. 400-0029; Renal Panel Plus, Cat. No. 400-0027; Basic Metabolic Panel Plus, Cat. No. 400-0031; Liver Panel Plus, Cat. No. 400-0003; Metlyte +CRP, Cat. No. 400-0034.

Endogenous analytes were value assigned on the Roche Cobas Mira Plus and Mindray BS-200 using Kamiya and Sekisui reagents.

Values are assigned by assaying 6 randomly selected vials from each manufacturing lot. Vials are measured in duplicate and across 2 or more instruments for each Abaxis Xpress panel listed above. Value assignment is performed within 30 days of manufacturing date. Vials used for value assignment are to be tested within 5 days after product is thawed.

Performance Testing:

The closed vial stability of CONE-TROL Liquid Chemistry Control at 2-8°C has been determined from real time stability testing. CONE-TROL Liquid Chemistry Control was stored closed vial at 2-8°C, as described in the package insert, for 33 days. Results indicate acceptable stability through 33 days.

The open vial stability of CONE-TROL Liquid Chemistry Control at 2-8°C has been determined from real time stability testing. After opening, CONE-TROL Liquid Chemistry Control was stored at 2-8°C for 15 days. To simulate expected handling conditions, vials were removed from refrigerator daily (excluding weekends), opened, and returned to refrigerator. Results indicate acceptable stability through 15 days.

The shelf life of CONE-TROL Liquid Chemistry Control at <-20°C has been determined from real time stability testing. CONE-TROL Liquid Chemistry Control was stored closed vial at -20°C, as described in the package insert, for 254 days. Results indicate acceptable stability through 254 days. Real time studies will be ongoing to support the shelf life of this product.

Summary:

The information provided in this pre-market notification demonstrates that CONE-TROL Liquid Chemistry Control is substantially equivalent to Liquid Assayed Multiqual Control (k011867). Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate device. The information supplied in this pre-market notification provides reasonable assurance that the CONE-TROL Liquid Chemistry Control is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 24 2012

Cone Bioproducts
c/o William K. Cone
1012 N. Austin St.
Sequin, TX 78155

Re: k121759
Trade Name: CONE-TROL Liquid Chemistry Controls
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: June 1, 2012
Received: June 15, 2012

Dear Mr. Cone:

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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number (if known): k121759

Device name: CONE-TROL Liquid Chemistry Controls

Indications for Use:

CONE-TROL Liquid Chemistry Control is a human liquid control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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) 121759