K103403

FEB - 4 2011

510(k) Summary

Submitter's Name/Address
Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Contact Person
Linda Morris
Senior Regulatory Specialist, MS 2-11
Regulatory Affairs
(972) 518-6711
Fax (972) 518-7479
Email: Linda.Morris@Abbott.com

Date of Preparation of this Summary:	January 14, 2011
Device Trade or Proprietary Name:	Abbott Clinical Chemistry Multiconstituent Calibrator
Device Common/Usual Name or Classification Name:	Multiconstituent Calibrator (MCC)
Classification Number/Class:	21 CFR 862.1150/ Class II (Calibrator, Multi-Analyte Mixture)
Product Code:	JIX

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

The assigned 510(k) number is: _(k)103403_____.

Device Description:

Original (Abbott Clinical Chemistry MCC (k981706)
A multi-Analyte Calibrator - human serum based, liquid ready-to-use calibrator containing Albumin, Calcium, Cholesterol, Creatinine, Glucose, Phosphorus, Total Protein, Triglyceride, Urea and Uric Acid.

Modified Abbott Clinical Chemistry MCC (k103403)
A multi-Analyte Calibrator - human serum based, liquid ready-to-use calibrator containing Albumin, Calcium, Cholesterol, Creatinine, Glucose, Iron, Lactate, Magnesium, Phosphorus, Total Protein, Triglyceride, Urea and Uric Acid.

Description of modifications:
The modified Abbott Clinical Chemistry Multiconstituent Calibrator is substantially equivalent to the original Multiconstituent Calibrator (K981706). The modifications consisted of certification of the following new analytes:

1. Iron
2. Lactate
3. Magnesium

These modifications did not significantly change the safety and effectiveness of the device as demonstrated in the Performance Characteristics Summary.

Intended Use:
For use in calibration of the Albumin, Calcium, Cholesterol, Creatinine, Glucose, Iron, Lactate, Magnesium, Phosphorus, Total Protein, Triglyceride, Urea and Uric Acid assays.

Indications for use:
This is an in vitro diagnostic product intended for use as a calibration serum in clinical chemistry assays. The MCC contains 13 analytes in a liquid human serum based matrix. The concentrations and activities are suitable for calibration of the Abbott ARCHITECT c8000 System. Constituent concentrations are available at 2 levels.

Predicate Device Description: MCC (k981706)

- Human serum based, liquid ready-to-use
- Containing Albumin, Calcium, Cholesterol, Creatinine, Glucose, Phosphorus, Total Protein, Triglyceride, Urea and Uric Acid
- Shelf-life of 20 months demonstrated by real time testing

Modified MCC Device:

- Human serum based, liquid ready-to-use.
- Containing Albumin, Calcium, Cholesterol, Creatinine, Glucose, Iron, Lactate, Magnesium, Phosphorus, Total Protein, Triglyceride, Urea and Uric Acid
- Shelf-life of 20 months was demonstrated by comparison with predicate using accelerated studies.
- The modifications are the addition of Iron, Lactate and Magnesium (at physiological levels) to the formulation.
- These modifications did not significantly change the safety and effectiveness of the device. The stability data confirms that the stability of the new formulation conforms to the stability claims of the previous formulation and traceability to reference materials using the same reference methods has been demonstrated to be substantially equivalent to the predicate device.

In determining substantial equivalence, a direct comparison of new and predicate device was performed, refer to table below.

Attributes	Predicate MCC (k)981706	Modified MCC (k)103403
Intended Use	For use in the calibration of Albumin, Calcium, Cholesterol, Creatinine, Glucose, Phosphorus, Total Protein, Triglyceride Urea and Uric Acid assays.	Same plus Iron, Lactate, and Magnesium
Component	Human serum matrix containing Albumin, Calcium, Cholesterol, Creatinine, Glucose, Phosphorus, Total Protein, Triglyceride Urea and Uric Acid.	Same plus Iron, Lactate, and Magnesium
Storage	2 to 8° C	Same
Shelf-life Stability	20 months from date of manufacture	Same
Open-vial Stability	7 days when stored at 2 to 8 °C or 24 hours when stored at 15 to 30 °C	Same

Value assignment and Traceability:

Value assignment is performed as follows:

- The testing is performed independently for each of the analytes, using one Abbott Architect c8000 System.
- For each analyte, system suitability (validity) is verified by calibrating and testing controls with pre-defined ranges.
- NIST standards are used for applicable analytes (refer to table on the next page for a list of all standards used).
- The standards may need to be weighed, dissolved and/or diluted to prepare a solution of appropriate concentration for the value assignment.
- 20 replicates of each tested calibrator level and of each respective standard solution are tested.
- The mean analyte values are calculated using the concentration of the standard solution and the absorbance values of the standard and the tested calibrator.
- The mean analyte values are verified by calibrating the system with the newly value-assigned calibrator, and measuring the reference standard solutions.
- Acceptance criterion: the mean value obtained for the reference standard solution must be within 5% from the known standard concentration.

Standardization/ Traceability information:

Analyte	Reference Material	Reference Method
Albumin	ERM-DA470	Gravimetric
Calcium	NIST SRM 956	Coulometric Titration
Cholesterol	Human Cholesterol (Abell-Kendall verification)	Volumetric
Creatinine	NIST SRM 967 and 914	IDMS
Glucose	NIST SRM 965	IDMS
Iron	NIST SRM 3126	Gravimetric
Lactic Acid	Reagent grade lactate	Gravimetric
Magnesium	NIST SRM 956	IDMS
Phosphorus	NIST 186-I/2186-I	Gravimetric
Total Protein	NIST SRM 927	Gravimetric
Triglyceride	ACS Grade Glycerol	Gravimetric
Urea Nitrogen	NIST SRM 909	IDMS
Uric Acid	NIST SRM 909	IDMS

Stability:
The expiration date claim is 20 months from product dispensing. Open vial stability claim is 7 days at 2-8 °C and 24 hours at room temperature (15-30 °C).

Data to support shelf-life stability of 20 months was established by accelerated stability studies on Architect c8000 Systems.

Open vial stability was established by incubating opened calibrator vials at 30°C for 28 hours, and at 2-8°C for 7 days, both with 3 calibrator lots. Results of the open vials (means of at least three replicates) were compared to those of freshly opened calibrator vials.

Conclusion:

The modified Abbott Clinical Chemistry Multiconstituent Calibrator (MCC) is substantially equivalent to the Abbott Clinical Chemistry Multiconstituent Calibrator as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

FEB 04 2011

Abbott Laboratories
c/o Linda Morris
Senior Regulatory Specialist
1921 Hurd Drive
Irving, TX, 75038, USA

Re: k103403
Trade/Device Name: Abbott Clinical Chemistry Multiconstituent Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, Multi-Analyte Mixture
Regulatory Class: Class II
Product Code: JIX
Dated: January 21, 2011
Received: January 21, 2011

Dear Ms. Morris

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

Indications for Use Form

510(k) Number (if known): (k)103403

Device Name: Abbott Clinical Chemistry Multiconstituent Calibrator

Indications for Use:

The Abbott Clinical Chemistry Multiconstituent Calibrator is an in vitro diagnostic product intended for use as a calibration serum in clinical chemistry assays. The MCC contains 13 analytes in a liquid human serum based matrix. The concentrations and activities are suitable for calibration of the Abbott ARCHITECT *c*8000 System. Constituent concentrations are available at 2 levels.

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

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