K062855

510(k) Summary

NOV 2 2 2006

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

Date of Preparation of this Summary:	September 18, 2006
Device Trade or Proprietary Name:	Calcium
Device Common/Usual Name or Classification Name:	Calcium
Classification Number/Class:	Class II / 862.1145
Product Code:	CJY

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: K062855

Test Description:

Calcium is an in vitro diagnostic assay for the quantitation of Calcium in human serum, plasma, or urine. Arsenazo-III dye reacts with calcium in an acid solution to form a blue-purple complex. The color developed is measured at 660 nm and is proportional to the calcium concentration in the sample.

Substantial Equivalence:

The Calcium assay is substantially equivalent to the Abbott Calcium (K981578) on the AEROSET and ARCHITECT *c*8000 System. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are Arsenazo Dye Methodology.
- Both assays can be used for the quantitation of Calcium.
- Both assays yield similar results.
- Both assays use serum, plasma, and urine

Differences:

None

Intended Use:

The Calcium assay is used for the quantitation of Calcium in human serum, plasma, or urine.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET and ARCHITECT *c*8000 Systems. The Calcium assay, LN 3L79, method comparison yielded acceptable correlation with the Abbott Calcium assay, LN 7D61, (K981578) on the AEROSET and ARCHITECT *c*8000 Systems (Predicate Device). The AEROSET System showed a correlation coefficient of 0.9993, slope of 0.96, and Y-intercept of 0.31 mg/dL for the serum application and a correlation coefficient of 0.9994, slope of 0.95, and Y-intercept of 0.17 mg/dL for the urine application when compared to the Predicate Device. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9989, slope of 0.96, and Y-intercept of 0.31 mg/dL for the serum application and a correlation coefficient of 0.9986, slope of 0.94, and Y-intercept of 0.17 mg/dL for the

urine application when compared to the Predicate Device. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9979, slope of 1.00, and Y-intercept of 0.04 mg/dL for the serum application and a correlation coefficient of 0.9991, slope of 0.99, and Y-intercept of 0.00 mg/dL for the urine application when compared to the AEROSET System. The Calcium assay method comparison yielded acceptable correlation between the AEROSET System and the ARCHITECT *c*8000 System.

Precision studies were conducted using the Calcium assay. On the AEROSET System, the total %CV for Level 1 is 1.01%, and Level 2 is 0.82% for the serum application and the total %CV for Level 1 is 0.74%, and Level 2 is 0.65% for the urine application. On the ARCHITECT *c*8000 System, the total %CV for Level 1 is 1.23%, and Level 2 is 0.95% for the serum application and the total %CV for Level 1 is 0.72%, and Level 2 is 0.66% for the urine application.

The Calcium assay is linear from 2 to 24 mg/dL for the serum and urine applications. The limit of quantitation (sensitivity) of the Calcium assay is 1.0 mg/dL for the serum and urine applications.

These data demonstrate that the performance of the Calcium assay is substantially equivalent to the performance of the Abbott Calcium assay, LN 7D61, (K981578) on the AEROSET and ARCHITECT Systems.

Conclusion:

The Calcium assay on the AEROSET and the ARCHITECT *c*8000 Systems is substantially equivalent to the Abbott Calcium assay, LN 7D61, (K981578) on the AEROSET and ARCHITECT Systems as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Linda Morris
Senior Regulatory Specialist, MS 2-11
Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

NOV 2 2 2006

Re: k062855
Trade/Device Name: Calcium
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CJY
Dated: September 18, 2006
Received: September 25, 2006

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, 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

510(k) Number (if known): K062855

Device Name: Calcium

Indications For Use:

A calcium test system is a device intended to measure the total calcium level in serum, plasma, and urine. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

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

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K062855