510(k) Summary

MAY - 4 2006

Submitter's Name/Address
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Date of Preparation of this Summary:	February 3, 2006
Device Trade or Proprietary Name:	Carbon Dioxide
Device Common/Usual Name or Classification Name:	Carbon Dioxide
Classification Number/Class:	KHS/Class II

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: K060295 .

Test Description:

Carbon Dioxide is an in vitro diagnostic assay for the quantitative analysis of CO_2 in human serum or plasma. Carbon dioxide, as bicarbonate (HCO_3^-), and phospho(enol)pyruvate (PEP) are converted to oxalacetate and phosphate in the reaction catalyzed by phospho(enol)pyruvate carboxylase (PEPC). Malate dehydrogenase (MDH) catalyzes the reduction of oxalacetate to malate with the concomitant oxidation of reduced nicotinamide adenine dinucleotide (NADH) analog. The resulting decrease in absorbance at 404 nm is proportional to the CO_2 content in the sample.

Substantial Equivalence:

The Carbon Dioxide assay is substantially equivalent to the Carbon Dioxide (CO2L) assay (K032377) on the Hitachi 717 Analyzer. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro enzymatic assays.
- Both assays can be used for the quantitative analysis of carbon dioxide.
- Both assays yield similar results.
- Both assays are based on the PEP Carboxylase methodology.

Differences:

None

Intended Use:

The Carbon Dioxide assay is used for the quantitation of carbon dioxide (CO_2) in human serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® and ARCHITECT® *c*8000® Systems. The Carbon Dioxide assay method comparison yielded acceptable correlation with the Carbon Dioxide (CO2L) assay on the Hitachi 717 Analyzer. The AEROSET System showed a correlation coefficient of 0.994, slope of 0.99, and Y-intercept of – 0.20 mEq/L when compared to the Hitachi 717 Analyzer. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9893, slope of 0.98, and Y-intercept of – 0.75 mEq/L when compared to the Hitachi 717 Analyzer. The Carbon Dioxide assay method comparison yielded acceptable correlation between the AEROSET System and ARCHITECT *c*8000 System. The ARCHITECT c8000 System showed a correlation coefficient of 0.995, slope of 0.98 and Y-intercept of –0.55 mEq/L when compared to the AEROSET System. Precision studies were conducted using the Carbon Dioxide assay. On the AEROSET System, the total %CV for Level 1 is 2.0%, and Level 2 is 2.4%. On the ARCHITECT c8000 System, the total %CV for Level 1 is 2.1%, and Level 2 is 2.5%. The Carbon Dioxide assay is linear from 5 to 50 mEq/L. The functional sensitivity (limit of quantitation) of the Carbon Dioxide assay is 4 mg/dL and the limit of detection (LOD) 2 mEq/L. These data demonstrate that the performance of the Carbon Dioxide assay is substantially equivalent to the performance of the Carbon Dioxide (CO2L) assay on the Hitachi 717 Analyzer.

Conclusion:

The Carbon Dioxide assay is substantially equivalent to the Carbon Dioxide (CO2L) assay on the Hitachi 717 Analyzer 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

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MAY - 4 2006

Re: k060295
Trade/Device Name: Carbon Dioxide
Regulation Number: 21 CFR§862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Code: KHS
Dated: February 3, 2006
Received: February 15, 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.

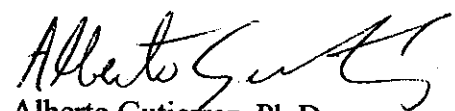
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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): K060295

Device Name: Carbon Dioxide

Indications For Use:

The Carbon Dioxide test system, reagent and calibrator, is a device intended to measure bicarbonate/carbon dioxide in plasma, and serum. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

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 IF NEEDED)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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