



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 2004

Ms. Marlene Walker
Director of Quality Systems
Diagnostic Chemicals Limited
Diagnostic Division
16 McCarville Street
West Royalty Industrial Park
Charlottetown, Prince Edward,
Canada C1E 2A6

Re: k042362
Trade/Device Name: Carbon Dioxide-L3K Assay
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Code: KHS
Dated: December 13, 2004
Received: December 14, 2004

Dear Ms. Walker:

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).

Page 2 –

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/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Carol C Benson for".

Cornelia B. Rooks, MA
Acting 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): K042362

Device Name: Carbon Dioxide-L3K Assay

Indications For Use:

For the quantitative determination of carbon dioxide in serum and plasma. For IN VITRO diagnostic use.

Elevated blood CO₂ is almost synonymous with respiratory acidosis. The latter is restricted to clinical conditions with a primary increase in carbon dioxide in the inspired air or increased metabolic production of carbon dioxide.

Decreased blood CO₂ is almost synonymous with respiratory alkalosis. The latter is restricted to clinical conditions with a primary decrease in carbon dioxide which can result from increased pulmonary ventilation due to mechanical ventilation or stimulation of the respiratory center (1).

Classic techniques for the measurement of carbon dioxide (CO₂) involve the addition of acid to liberate the carbon dioxide and the measurement of carbon dioxide thus released by either manometric, volumetric, or titrimetric techniques. These procedures are both time consuming and cumbersome. The DCL Carbon Dioxide L3K[®] assay is an enzymatic procedure, employing phosphoenolpyruvate carboxylase (PEPC) (2) and a stabilized NADH analog (3), which is easy to use and applicable to routine laboratory instrumentation.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 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

Page 1 of 1

510(k) K042362