



JUL 5 - 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Penny J. White
Regulatory Affairs, Coordinator, External
Diagnostic Chemicals Limited
16 McCarville Street
Charlottetown, PE CIA 2E6

Re: k051191
Trade/Device Name: Microalbumin Assay
Regulation Number: 21 CFR 866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: Class II
Product Code: DCF
Dated: May 5, 2005
Received: May 10, 2005

Dear Ms. White:

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.

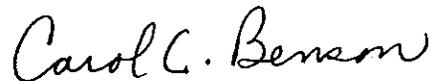
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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,



Carol C. Benson, M.A.
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): K051191

Device Name: Microalbumin Assay

Indications for Use:

For the quantitative determination of low levels of albumin in urine.

For IN VITRO diagnostic use.

Low levels of protein are normally excreted in the urine of healthy individuals. The uriniferous tubules and glomeruli filter out most of these excreted mucoproteins. Albumin, a protein of molecular weight of 50,000, is not easily filtered out and small amounts are excreted into the urine. Increased excretion of albumin (microalbuminuria) is an early indicator of glomerular disease (1,2).

Microalbuminuria is characterized by increased urinary excretion of albumin in the absence of overt nephropathy (3,4). Microalbumin is recognized as a strong predictor of impending nephropathy in Type I Diabetics and its mortality risk in diabetic patients (5). Early detection of microalbuminuria may be beneficial for treatment programs for diabetics because renal damage may be reversible if diabetes is well controlled at this stage.

Many of the methods traditionally used for measuring albumin lack the sensitivity and precision required for measuring microalbumin. The DCL Microalbumin Assay uses an immunoturbidimetric format which provides the sensitivity required for accurate determination of urinary microalbumin.

Prescription Use

AND/OR

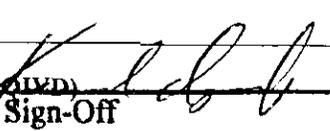
Over the Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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

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

Division Sign-Off 

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051191