



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 23 2002

Mr. Mike Berg
Diagnostic Chemicals Limited
2637 Eva Street
Laguna Hills, CA 92656

Re: k022538
Trade/Device Name: ImmunoDip™ Urinary Albumin Test
Regulation Number: 21 CFR 862.1645
Regulation Name: Urinary protein or albumin (nonquantitative) test system
Regulatory Class: Class I
Product Code: JIR
Dated: July 30, 2002
Received: August 1, 2002

Dear Mr. Berg:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022538

Device Name: ImmunoDip™ Urinary Albumin Test

Indications for Use:

For *IN VITRO* diagnostic use.

There are several kidney disease conditions that can produce high levels of albumin in urine (1). Determining albumin in the urine at the low levels measured by this test is helpful for early detection and treatment of patients at risk for renal (kidney) disease. Low but elevated urinary albumin levels, or microalbuminuria, refers to a level of the human protein albumin in urine above about 18 mg/L. Levels above 18 mg/L are not normally found in healthy individuals. These low but significant levels are not detectable with older dipstick assays. The ImmunoDip™ Urinary Albumin Test classifies samples as positive or negative based on their being above or below a level of 18 mg/L.

Conditions in which elevated levels of albumin in urine may be present include: Type 1 and Type 2 diabetes (2-8); hypertension (9, 10); and renal disease found in pregnancy (11). There are other less common causes as well. Diabetes is the largest single cause. One study found 45% of the insulin-dependent diabetics develop serious kidney disease (3). Testing for elevated levels of albumin in urine helps to identify those diabetics who are prone to kidney disease. Scientific studies indicate that proper control of blood glucose (blood sugar) levels and blood pressure help slow or prevent kidney damage (1, 9).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Alberto Sauter for Ivan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022538