DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 29 1998

Karen Callbeck, R.T.B.Sc.
Regulatory Affairs Coordinator
Diagnostic Chemicals Limited
16 First Street
West Royalty Industrial Park
Charlottetown, PE
Canada C1E, 1B0

Re: K981872
Salicylate-SL Assay
Regulatory Class: II
Product Code: DKJ
Dated: May 25, 1998
Received: May 28, 1998

Dear Ms. Callbeck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

Steven Gutman

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): K981872

Device Name: Salicylate-SL Assay

Indications for Use:

For the quantitative determination of salicylate in serum. For IN VITRO diagnostic use.

Salicylate is a common drug used for its analgesic and anti-inflammatory properties. Its accessibility leads to its implication in a large number of accidental ingestions by children and it is a common choice among adults and adolescents for attempted suicidal poisoning. (1)

Salicylate overdose results in disturbances of the central nervous system and the gastrointestinal tract as well as encephalopathy and renal failure. It represents an acute medical emergency and rapid quantitation of the drug is necessary for effective patient management. (2)

Salicylate has been traditionally measured by the "Trinder Reaction" which is based on the interaction between salicylate and ferric ions. This test however is not specific and requires extraction or centrifugation which inhibit the automation of the test.

This enzymatic Salicylate Assay provides a rapid, specific and simplified method for salicylate determination. It is based on the action of salicylate hydroxylase on salicylate and NADH which results in a decrease in absorbance proportional to the amount of salicylate present. (3) The test can be adapted to automated instruments resulting in rapid, accurate results required by physicians.

Carol C Benson for Alfred Montgomery

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981872

✓ Prescription Use