



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

FEB 12 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: K974874  
Trade Name: Bilirubin-SL (TOTAL) Assay  
Regulatory Class: II  
Product Code: CIG 75  
Dated: December 19, 1997  
Received: December 29, 1997

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 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.

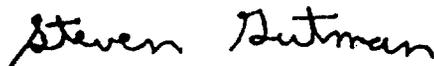
Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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): K 97 4874

Device Name: Total Bilirubin-SL Assay

**Indications for Use:**

For the quantitative determination of Total Bilirubin in serum. For IN VITRO diagnostic use. Bilirubin is a bile pigment normally found in serum as a result of red cell destruction. It is a product of hemoglobin breakdown by the reticuloendothelial system and exists in two forms. Unconjugated (indirect) bilirubin is transported to the liver bound by albumin where it becomes conjugated (direct) with glucuronic acid and excreted.

The elevation of total serum bilirubin may occur due to hemolytic processes, liver disease, or a disorder of the biliary tract.

Traditional methods of measuring bilirubin are based on the reaction of bilirubin with a diazo reagent to form the colored compound: azo-bilirubin. The diazo reaction can be accelerated by the addition of various chemicals. For example, Malloy-Evelyn (1) used ethanol, Jendrassik-Grof (2) used caffeine, and Walters-Gerarde (3) used DMSO. Modifications of these methods included the addition of surfactants as solubilizing agents (4).

In this method, a 2,4-dichlorophenyl diazonium salt is used as the diazo reagent and the reaction is facilitated by the use of a surfactant.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

P. Bernhardt (for A. Montgomery)  
(Division Sign-Off)  
Division of Clinical Laboratory Services  
510(k) Number K 974874

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use