



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**MAY 14 2002**

Ms. Nancy Olscamp  
External Regulatory Affairs Coordinator  
Diagnostic Division  
Diagnostic Chemical Limited  
16 McCarville Street  
Charlottetown  
PE Canada C1E 2A6

Re: k020816  
Trade/Device Name: Iron-PC-SL Assay  
Regulation Number: 21 CFR 862.1410  
Regulation Name: Iron (non-heme) test system  
Regulatory Class: Class I  
Product Code: JIY  
Dated: March 12, 2002  
Received: March 13, 2002

Dear Ms. Olscamp:

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.

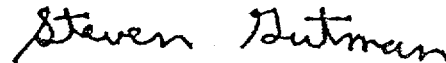
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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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) Notification

Iron-PC-SL Assay, Cat. No. 151-10, 151-26



**Diagnostic Chemicals Limited**

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**INDICATIONS FOR USE**

510(k) Number (if known):           K020816          

Device Name:           Iron-PC-SL Assay          

**Indications for Use:**

An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis and chronic renal disease.

For the quantitative determination of iron in serum and heparinized plasma.

          Jean Cooper            
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number           K020816          

For IN VITRO diagnostic use.

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

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

Prescription Use

OR

Over-The-Counter  
Use

(Per 21 CFR 801.109)