DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 8 2004

Borek Janik, Ph.D.
Official Correspondent
Sebia
13805 Waterloo
Chelsea, MI 48118

Re: k040925
Trade/Device Name: Normal Control Serum
Hypergamma Control Serum
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: April 5, 2004
Received: April 15, 2004

Dear Dr. Janik:

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).

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040925

Device name:

1. NORMAL CONTROL SERUM PN 4785
2. HYPERGAMMA CONTROL SERUM PN 4787

Indications For Use:

Sebia Normal Control Serum is indicated for the quality control of densitometric quantification of electrophoretic separations of human serum proteins, lipoproteins and lipoprotein-cholesterol fractions on Sebia HYDRAGEL™ agarose gels. The Normal Control Serum is also indicated for the quality control of quantification of electrophoretic separations of human serum proteins on Sebia CAPILLARYS™, the capillary electrophoresis system.
The constituents of the Normal Control Serum are within the concentration ranges (g/dL) expected in normal individuals. The relative (%) distribution of individual fractions and the densitometric profile also reflect normal distribution.

Sebia Hypergamma Control Serum is indicated for the quality control of densitometric quantification of electrophoretic separations of human serum proteins on HYDRAGEL agarose gels and for the quality control of quantification of electrophoretic separations of human serum proteins on CAPILLARYS, the capillary electrophoresis system.
The concentration of gammaglobulins in this control is elevated above the normal level.

The control values for all applicable tests for which the control materials are intended are determined for each lot of Control Serum. The control values are published in the product package insert included with each package of the Control Serum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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

510(k) K040925

(Optional Format 1-2-96)