



Sebia Inc, USA
c/o Ms. Karen Anderson, MT (ASCP)
Director of Technical and Quality Assurance
1705 Corporate Drive, Suite 400
Norcross, GA 30093

NOV - 7 2011

Re: k101863

Trade/Device Name: IT/IF Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I (Reserved)
Product Codes: JJY, CFF, DFH, DEH, CEF
Dated: October 12, 2011
Received: October 13, 2011

Dear Ms. Anderson:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

Page 2 – Ms. Karen Anderson

will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

Maria Chan, Ph.D.

Director

Division of Immunology and Hematology Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101863

Device Name: IT / IF CONTROL

Indications For Use:

The IT / IF Control is designed for the qualitative quality control of the detection and characterization of human monoclonal immunoglobulins (IgG, IgA, IgM, Kappa and Lambda) with the electrophoresis methods:

- Immunotyping performed using capillary electrophoresis on SEBIA MINICAP instrument,
- Immunofixation methods: SEBIA HYDRAGEL IF, HYDRAGEL IF Penta, HYDRAGEL BENCE JONES (Standard mask and Dynamic mask) performed using the HYDRASYS and HYDRASYS 2 instruments and the K20 electrophoresis chamber.

The IT / IF Control is designed for laboratory use. It should be used (with its barcode label for MINICAP procedure) like a human serum sample.

The electrophoretic pattern obtained is specific for each batch of IT/IF control.

For *In Vitro* Diagnostic Use.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

Page 1 of 1

510K K101863