DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

FEB 2 2 2010

Sebia
c/o Ms. Karen Anderson, MT(ASCP)
Director of Technical Training and Regulatory
1705 Corporate Drive, Suite 400
Norcross, Georgia 30093

Re: k091283
Trade/Device Name: CAPILLARYS NEONAT Hb, PN 2006
Hb AF CONTROL, PN 4777
Regulation Number: 21 CFR 864.7415
Regulation Name: Abnormal hemoglobin assay
Regulatory Class: Class II
Product Code: GKA
Dated: February 5, 2010
Received: February 12, 2010

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 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 M. 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): K091283

Device Name: CAPILLARYS NEONAT Hb, PN 2006

Indications For Use:

The CAPILLARYS NEONAT Hb kit is designed for the separation of the normal hemoglobins (F and A) in blood samples from human new-borns, and for the detection of the major hemoglobin variants (S, C, E, D and Bart's), by electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 2 System. The CAPILLARYS NEONAT Hb kit is designed for laboratory use.

The CAPILLARYS 2 is an automated analyzer which performs a complete hemoglobin profile for the qualitative analysis of hemoglobins. The assay is performed on the hemolysate of whole blood samples previously collected on filter paper.

For *In Vitro* Diagnostic Use.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K091283

Indications for Use

510(k) Number (if known):

Device Name: Hb AF CONTROL, PN 4777

Indications For Use:

The Hb AF Control is designed:
- for the migration control before starting a new analysis sequence and for the qualitative quality control, for human hemoglobins A and F with the SEBIA CAPILLARYS NEONAT Hb electrophoresis procedure used with the CAPILLARYS 2 system, and,
- for the quantitative quality control for detection of the human hemoglobins A, F and A2 with the SEBIA electrophoresis procedures : HYDRAGEL HEMOGLOBIN(E) used with the HYDRASYS system, CAPILLARYS HEMOGLOBIN(E) used with the CAPILLARYS system and MINICAP HEMOGLOBIN(E) used with the MINICAP system.

The Hb AF Control is designed for laboratory use. It should be used (with its bar code label for the CAPILLARYS and MINICAP procedures) like a normal human blood.
The values obtained must fall within the range provided with each batch of Hb AF Control.

For *In Vitro* Diagnostic Use.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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