DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 27 2005

Sebia, Inc.
c/o Mr. Borek Janik
400-1705 Corporate Drive
Norcross, GA 30093

Re: k042939
Trade/Device Name: CAPILLARYS IMMUNOTYPING, PN 2100
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins (A,G,M,D,E) Immunological Test System
Regulatory Class: Class II
Product Code: CFF, DFH, DEH, CEF
Dated: October 12,2004
Received: October 25, 2004

Dear Mr. 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 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.

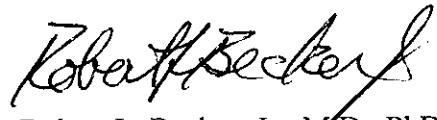
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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 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), please contact the Office of Compliance at (240) 276-0131. 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,



Robert L. Becker, Jr., M.D., PhD
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): K042939

Device name: **CAPILLARYS IMMUNOTYPING, PN 2100**

Indications For Use:

The CAPILLARYS IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human serum with the SEBIA CAPILLARYS System, for capillary electrophoresis. It is used in conjunction with the CAPILLARYS PROTEIN(E) 6 or CAPILLARYS ß1-ß2^{+} kits designed for serum proteins separation into 6 major fractions in alkaline buffer (pH 9.9).

The CAPILLARYS system performs all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each sample is mixed with individual antisera that are specific against gamma (IgG), alpha (IgA) and mu (IgM) heavy chains, and kappa (free and bound) light chains and lambda (free and bound) light chains.

The proteins fractions, separated in silica capillaries, are directly detected by their absorbance at 200 nm. The electrophoregrams are evaluated visually by comparing the profile of the untreated sample with the individual profiles treated with the respective antisera. Monoclonal immunoglobulins are thus detected and identified.

Identification of Monoclonal immunoglobulins is essential for the classification of monoclonal gammopathies by the class and type of involved immunoglobulins.
"For In Vitro Diagnostic Use."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Maria M. Chan

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K042939