



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEBIA, Inc.
c/o Ms. Karen Anderson
Director of Technical and Regulatory
400-1705 Corporate Drive, Suite 400
Norcross, GA 30093

APR 17 2009

Re: k082085

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: April 03, 2009
Received: April 06, 2009

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 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); 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

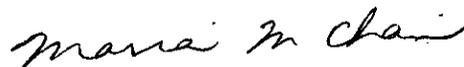
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substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

510(k) Number (if known):k082085

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 urine and serum with the CAPILLARYS System, SEBIA, for capillary electrophoresis. It is used in conjunction with the CAPILLARYS PROTEIN(E) 6 kit, SEBIA, designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9).

The CAPILLARYS performs all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each urine or serum sample is mixed with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) light chains and lambda (free and bound) light chains, respectively.

The proteins, separated in silica capillaries, are directly detected by their absorbance at 200 nm.

The electrophoregrams are evaluated visually to detect the presence of specific reactions with the suspect monoclonal proteins.

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
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)

Maura McClan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 082085