DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Sebia, Inc.
c/o Borek Janik, Ph.D.
Morax-Official Correspondent
13805 Waterloo
Chelsea, Michigan 48118

NOV - 4 2003

Re: k033277
Trade/Device Name: HYDRAGEL 3 CSF ISOFOCUSING PN 4353
HYDRAGEL 9 CSF ISOFOCUSING PN 4355
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D, E Immunological Test System
Regulatory Class: II
Product Code: CFF
Dated: October 4, 2003
Received: October 10, 2003

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). 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 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033277

(Special 510(k): Device Modification)

Device name:	HYDRAGEL 3 CSF ISOFOCUSING	PN 4353
	HYDRAGEL 9 CSF ISOFOCUSING	PN 4355

Indications For Use:

The HYDRAGEL 3 CSF ISOFOCUSING and HYDRAGEL 9 CSF ISOFOCUSING kits are designed for the qualitative detection of oligoclonal bands in the electrophoretic patterns of cerebrospinal fluid (CSF) and confirmation of their immunoglobulin character. The use of anti-IgG antisera permits to prove or disprove the "true" IgG character of oligoclonal banding. Visual, comparative interpretation of immunofixation patterns of IgG in high resolution isoelectric separations of CSF and serum proteins from the same patient allows detection of oligoclonal banding that represents intrathecal synthesis of immunoglobulins.

The HYDRAGEL 3 CSF ISOFOCUSING and HYDRAGEL 9 CSF ISOFOCUSING kits are indicated when certain diseases of the central nervous system (CNS), such as multiple sclerosis, are suspected and the detection of oligoclonal banding and inflammatory processes (intrathecal synthesis of immunoglobulins) can aid to the diagnosis.

The use of enzyme labeled antibodies increases the sensitivity of detection so that the analysis can be generally performed on unconcentrated CSF.

The only difference between the 3 CSF and 6 CSF kits is in the intended number of samples per gel: 3 and 9 CSF/serum sample pairs, respectively.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. Pleus for T. J. Ulatowski

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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

510(k)

(Optional Format 1-2-96)