JUN 1 1 2007

K063498

SEBIA Inc.
Suite 400, 1705 Corporate Drive
NORCROSS, GA 30093 **Tel: (770) 446 3707 - 3704**
USA **Fax: (770) 446 8511**

510(k) Summary

Prepared: June 6, 2007

Applicant	**SEBIA, INC.** 400-1705 corporate dr. Norcross, GA 30093
Manufacturer	**SEBIA** Parc technologique Leonard de vinci Rue Leonard de vinci CP 8010 Lisses, 91080 EVRY Cedex, France
Submitter	**SEBIA, INC**
Address	400-1705 corporate dr. Norcross, GA 30093
Trade/proprietary Name	HYDRAGEL 18 A1AT ISOFOCUSING (PN 4356)
Common Names	Alpha-1 Antitrypsin phenotype Test
Classification name	Alpha-1 Antitrypsin phenotype Test
Classification number	21 CFR 866.5510. 21 CFR 866.5130

Device Description:
The configurations of the HYDRAGEL 18 A1AT ISOFOCUSING kit consist of the components summarized in Tables I and II in main 510(k) submission. Each kit is supplied with Package Insert which contains instruction for use and all the necessary information on the reagents needed to run the tests that are sold separately. Each Package Insert also contains information on storage conditions, shelf-life and signs of deterioration of the kit components and the reagents sold separately, and on interpretation of the results.

Intended Use:
The HYDRAGEL 18 A1AT ISOFOCUSING kit is designed for the qualitative detection and identification of the different phenotypes of Alpha-1 antitrypsin (A1AT). Phenotyping results in conjunction with clinical findings and other laboratory assays aid in the diagnosis of Alpha-1 antitrypsin deficiency The analysis is performed on human sera separated into electrophoretic patterns ready for qualitative analysis. The procedure includes isoelectrofocusing on agarose gel, performed on the semi-automatic HYDRASYS system, followed by immunofixation with anti-Alpha-1 antitrypsin antiserum. The use of enzyme labeled anti-Alpha-1 antitrypsin antiserum enhanced the detection and identification of the different phenotypes.

Substantial Equivalence Discussion:

For qualitative characterization of Alpha-1 antitrypsin phenotypes by isoelectric focusing and immunofixation with peroxidase labeled antiserum, the HYDRAGEL 18 A1AT ISOFOCUSING kit was compared to a predicate technique currently used in clinical diagnostic laboratories, which is based on polyacrylamide gel isoelectric focusing followed by staining of separated Alpha-1 antitrypsin isoforms with Coomassie Blue staining solution. These two techniques were found, experimentally and conceptually, substantially equivalent in assay principle, function, use, safety and effectiveness.

Parameters	**Sebia**	**ARUP**	**Specialty Laboratories**	**University of California, Medical center**
510(k) Number	Not Assigned	Don't have	Don't have	Don't have
Company name	HYDRAGEL 18 A1AT ISOFOCUSING kit	Alpha-1-Antitrypsin Phenotype	Alpha-1- Anti trypsin phenotypr without total AAT	Alpha-1-Antitrypsin Phenotype test
Method	Isoelectric Focusing	Isoelectric Focusing/ Immunoturbidimetric	Isoelectric Focusing	Isoelectric Focusing
Phenotype detection	Yes	Yes	Yes	Yes
Results are qualitative	Yes	Yes	Yes	Yes
Sample collected	Serum	Serum	Serum	Serum

In their concept and principle, and the techniques and the procedures used, the SEBIA HYDRAGEL 18 A1AT ISOFOCUSING tests are also similar to other products currently marketed in the USA, notably to SEBIA HYDRAGEL 3 & 9 CSF ISOFOCUSING kits.

HYDRASYS uses semi-automated electrophoresis system, such as described in the 510(k) premarket notification Ref. No. K033277 for which FDA clearance was issued on November 4, 2003

Assessment of Performance:

Performance study and comparisons of the HYDRAGEL 18 A1AT ISOFOCUSING KITS with polyacrylamide gels isoelectric focusing and comassie blue staining was done.

For Alpha-1 antitrypsin phenotypes characterization, the SEBIA HYDRAGEL 18 A1AT ISOFOCUSING in vitro diagnostic test is substantially equivalent to a predicate device, a polyacrylamide gel isoelectric focusing technique currently used in clinical diagnostic

laboratories in the United States. Both tests are intended for qualitative analysis of Alpha-1 antitrypsin isoforms from human serum samples. All these products utilize isoelectric focusing to separate the isoforms on a suitable medium. The separated isoforms are then visualized by immunological reactions with a peroxidase labeled antiserum and a staining reagent or by Coomassie Blue staining solution. In both tests, the resulting patterns are evaluated visually.
Data are presented documenting substantial equivalency of the SEBIA and the polyacrylamide gel isoelectric focusing technique for Alpha-1 antitrypsin phenotype characterization. These devices were found experimentally and conceptually equivalent in assay principle, function, use, safety and effectiveness.

Other testing:

A - Concordance study
B - Within-gel reproducibility
C - Gel-to-gel and lot-to-lot reproducibility
D - Sensitivity study

Testing for Controls:

A- Validation testing:
-Reproducibility within gel and,
-Reproducibility between gels on 4 gels and on 12 gels.

B-Stability testing

Conclusion:

Performance studies of HYDRAGEL 18 A1AT ISOFOCUSING yielded satisfactory results in terms of concordance, reproducibility, sensitivity, validation and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

JUN 11 2007

Re: k063498
Trade/Device Name: HYDRAGEL 18 A1AT ISOFOCUSING Kit and A1AT Controls
Regulation Number: 21 CFR 866.5130
Regulation Name: Alpha-1-antitrypsin immunological test system
Regulatory Class: Class II
Product Code: OBZ, JJX
Dated: June 5, 2007
Received: June 6, 2007

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 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). 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 (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., 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): k063498

Applicant: SEBIA, INC.

Device Name: HYDRAGEL 18 A1AT ISOFOCUSING (PN 4356)

INDICATIONS FOR USE:

The HYDRAGEL 18 A1AT ISOFOCUSING kit is designed for the qualitative detection and identification of the different phenotypes of Alpha-1 antitrypsin (A1AT). Phenotyping results in conjunction with clinical findings and other laboratory assays aid in the diagnosis of Alpha-1 antitrypsin deficiency The analysis is performed on human sera separated into electrophoretic patterns ready for qualitative analysis. The procedure includes isoelectrofocusing on agarose gel, performed on the semi-automatic HYDRASYS system, followed by immunofixation with anti-Alpha-1 antitrypsin antiserum. The use of enzyme labeled anti-Alpha-1 antitrypsin antiserum enhanced the detection and identification of the different phenotypes.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 063498

510(k) Number (if known): k063498

Applicant: SEBIA, INC.

Device Name: A1AT CONTROLS (PN 4770)

INDICATIONS FOR USE:

For *In Vitro* Diagnostic Use.

Intended Use
The A1AT Controls are designed for the migration control of the human Alpha-1 antitrypsin isoforms pattern obtained with HYDRAGEL 18 A1AT ISOFOCUSING * isoelectric-focusing procedure.
The A1AT Controls should be used as human sera.

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 Device Evaluation (ODE)

Maria M Chan
Division Sign-Off

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