



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

JUN -1 2008

Re: k080916
Trade/Device Name: CAPILLARYS URINE, PN 2012
Regulation Number: 21 CFR 866.5150
Regulation Name: Bence Jones proteins immunological systems
Regulatory Class: Class II
Product Code: JKM
Dated: June 16, 2008
Received: June 19, 2008

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

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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 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. 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.
Acting Division 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: K080916
(Special 510(K): Device modification)

Device name: **CAPILLARYS URINE, PN 2012**

Indications For Use:

The CAPILLARYS URINE kit is designed for the preparation of urine samples before separation of human urine proteins in alkaline buffer (pH 9.9) with the CAPILLARYS system. The CAPILLARYS performs automatically all sequences to obtain a urinary protein profile for qualitative analysis. The proteins, separated in silica capillaries, are directly detected at an absorbance of 200 nm. The electrophoretograms can be interpreted visually to detect for any pattern abnormalities (monoclonal components, particularly Bence Jones proteins and other urinary proteins). The test results should be used in conjunction with clinical and laboratory findings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use

(Optional Format 1-2-96)

Maria M Chan
Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety
K080916